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Legacy

Dedicated to improving the lives of all patients afflicted with cancer

Roche Tissue Diagnostics
Roche Diagnostics
Delivering medical value and testing efficiency

Roche is a leader in research-focused healthcare with combined strengths in diagnostics and pharmaceuticals. The world’s largest biotech company, Roche is the world leader in in vitro diagnostics and tissue-based cancer diagnostics and is a frontrunner in diabetes management.

Spanning the entire spectrum of diagnostics users

Combined strengths of the Roche Group

Leadership in Pharma  Leadership in Diagnostics
Roche Tissue Diagnostics
Providing what your lab needs to advance patient care

Like you, we're passionate about the patient behind every slide. And we're committed to empowering your lab with advanced solutions to transform patient care. As part of the world's leading healthcare company, we're dedicated to helping pathology professionals deliver accurate, reliable results that help inform decision making to advance patient care.

Ensuring the identity of David's specimen

VENTANA VANTAGE Workflow Solution
Complete chain of custody to mitigate risk of misidentification

Protecting the integrity of Sue's slide

VENTANA HE 600 system
Individual H&E slide staining to help you safeguard your patients

Pathologist founded, patient focused

Building on the vision of Dr. Thomas Grogan, Roche Tissue Diagnostics continues to drive diagnostic innovation that transforms the practice of medicine to improve patients' lives.

Steering Leslie’s therapy in the right direction

VENTANA BenchMark Series Staining Platforms
Broad assay menu to help you deliver diagnostic confidence
Roche Tissue Diagnostics is transforming cancer diagnosis with the VENTANA total solution, addressing the needs of anatomic pathology labs and healthcare professionals to help them improve the lives of the patients they serve. Our broad portfolio includes integrated staining and workflow management platforms, digital pathology solutions and a robust menu of high-medical-value assays that help labs increase efficiency, improve patient safety and deliver medical value.

From the time a patient specimen arrives to delivery of test results, the VENTANA total solution enables your lab to provide accurate and reliable results in a timely manner. This helps patients get the right test, for the right treatment, at the right time.
What’s New
Improving lives through ongoing innovation

As part of Roche, we’re continuously investing in diagnostic tools that address unmet medical needs and provide information to help advance patient care.

VENTANA PD-L1 (SP142) Assay
Guiding immunotherapy

The first FDA-approved test predictive for TECENTRIQ® (atezolizumab) in urothelial carcinoma (UC) patients. Now also FDA approved to assess non-small cell lung cancer (NSCLC) patient treatment benefit from TECENTRIQ.

Learn more at PDL1ihc.com

VENTANA PD-L1 (SP142) Assay

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<tr>
<th>50 tests</th>
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<th>Cat. No.</th>
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<tbody>
<tr>
<td>07709374001</td>
<td>740-4859</td>
<td></td>
</tr>
</tbody>
</table>

See complete product details on page 91.
VENTANA ALK (D5F3) CDx Assay

50 tests Ordering Code Cat. No.
06687199001 790-4796

See complete product details on page 19.

anti-p40 (BC28) Mouse Monoclonal Primary Antibody

50 tests Ordering Code Cat. No.
07394200001 790-4950

See complete product details on page 87.

SOX-10 (SP267) Rabbit Monoclonal Primary Antibody

50 tests Ordering Code Cat. No.
07560389001 760-4968

See complete product details on page 98.

Desmoglein 3 (5G11) Mouse Monoclonal Primary Antibody

50 tests Ordering Code Cat. No.
07709470001 760-5060

See complete product details on page 51.

NKX3.1 (EP356) Rabbit Monoclonal Primary Antibody

50 tests Ordering Code Cat. No.
07859759001 760-5086

See complete product details on page 85.

For current product information, including the newest assays, visit usdiagnostics.roche.com/en/tissue/overview.html
**Olig2 (EP112) Rabbit Monoclonal Primary Antibody**

50 tests  
Ordering Code  
Cat. No.
07667973001  
760-5050

See complete product details on page 86.

**VENTANA PTEN (SP218) Rabbit Monoclonal Primary Antibody**

50 tests  
Ordering Code  
Cat. No.
07970200001  
790-5097

See complete product details on page 95.

**VENTANA PD-L1 (SP263) Rabbit Monoclonal Primary Antibody**

50 tests  
Ordering Code  
Cat. No.
07494190001  
790-4905

See complete product details on page 91.

**HPV mRNA ISH Probes**

RNA probes for detection of specific HPV mRNA localization in formalin-fixed, paraffin-embedded (FFPE) tissue, for use in laboratory developed tests.

<table>
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<td>HPV 11 mRNA Probe</td>
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<td>HPV 16 mRNA Probe</td>
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<td>HPV 18 mRNA Probe</td>
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<tr>
<td>HPV 33 mRNA Probe</td>
<td>07658869001</td>
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HPV 16 mRNA Probe, 40x magnification

Analyte Specific Reagents. Analytical and performance characteristics are not established.

For current product information, including the newest assays, visit usdiagnostics.roche.com/en/tissue/overview.html
Companion and Complementary Diagnostics

Transformative

Pioneering solutions that drive personalized healthcare
**Companion Diagnostics**

*Selective and predictive assays essential for personalized healthcare*

---

**A call to personalize the practice of medicine**

“Personalized healthcare is not holding a patient’s hand. It’s holding the intimate details of a patient’s test results to a brighter light and asking, ‘What am I missing?’”

— Tom Grogan, M.D., pathologist and founder of Ventana Medical Systems, Inc.

---

Linking the most accurate diagnosis with the most targeted and relevant therapeutic is the essence of personalized healthcare, offering the potential for more positive outcomes for the patient—saving lives and improving the quality of life.

**Our commitment to helping you deliver personalized healthcare**

In our mission to improve the lives of all patients afflicted with cancer, our goal is to empower you with the highest quality, most innovative tools to help deliver on the promise of personalized diagnostics and treatment. We’re committed to accelerating the development of new cancer tests that can help improve and extend patients’ lives by spanning the gap between generic and personalized treatment.

“Targeted diagnostic tests that help to improve medical decision-making not only offer clinical benefits for patients but are also attractive through health economic benefits to regulatory authorities and payers.”

— Severin Schwan, CEO, Roche

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**Helping Sonia get the right test at the right time**

Fast, reliable and standardized diagnostic tests can help physicians assess treatment options for cancer patients like Sonia. By identifying patients who express specific biomarkers, VENTANA companion diagnostic assays provide predictive information that aids in the choice of therapies. Targeted diagnostics and treatments offer cancer patients the potential for fewer side effects, improved quality of life, and better outcomes. With companion diagnostics helping patients get the right treatment at the right time, the promise of personalized healthcare becomes a reality.
VENTANA companion diagnostics

VENTANA companion diagnostics are fully automated to help improve quality and standardize testing, and can easily fit into your current workflow.

**VENTANA PATHWAY anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody:** Aids in the assessment of breast cancer patients for whom Herceptin® (trastuzumab) treatment is considered. For more information on the VENTANA PATHWAY anti-HER-2/neu (4B5) primary antibody, see page 67.

**VENTANA INFORM HER2 Dual ISH Assay:** The only fully automated PMA-approved HER2 molecular assay that allows evaluation of HER2 gene status with morphological context using brightfield microscopy.

Catalog Number: 780-4422  
Ordering Code: 05586640001

**VENTANA PATHWAY c-Kit (9.7):** Aids in the selection of gastrointestinal stromal (GIST) patients who may qualify for Gleevec®/Glivec® (imatinib mesylate) therapy. For more information on the PATHWAY anti-c-Kit primary antibody, see page 25.

**VENTANA ALK (D5F3) CDx Assay:** Fully automated, easy-to-score, 4-hour ALK IHC test that provides same-day results to aid in identifying non-small cell lung cancer (NSCLC) patients eligible for treatment with XALKORI® (crizotinib). For more information, see page 19.

In collaboration with leading pharmaceutical companies, we identify and develop innovative companion diagnostics to target those patients who are likely to respond to specific therapies.

- Well positioned to deliver personalized healthcare as part of Roche
- 13+ years of companion diagnostics development experience
- Experience & expertise expressing biomarkers across dozens of tissue types & indications
- In-house CAP/CLIA lab with 100+ prototype assays
- Collaborations with 55+ unique pharmaceutical partners
- 200+ biomarker projects ongoing at any one time
- A world leader in companion diagnostics for breast cancer
Complementary Diagnostics

Important information for drug-benefit decisions

Insights to guide immunotherapy decisions

Complementary diagnostic assays expand the array of tools available to help drive personalized healthcare and enable better outcomes for patients.

While not required for safe and effective use of a therapeutic drug, complementary diagnostic assays may provide additional information that helps physicians make informed treatment decisions.

VENTANA complementary diagnostics

The VENTANA PD-L1 (SP142) Assay is fully automated to help provide reliable, accurate results to enable timely diagnostic decisions and therapeutic choices.

VENTANA PD-L1 (SP142) Assay: The first and only FDA-approved test predictive for TECENTRIQ® (atezolizumab) in urothelial carcinoma (UC) patients. Now also FDA approved to assess non-small cell lung cancer (NSCLC) patient treatment benefit from TECENTRIQ®.

Catalog Number: 740-4859   Ordering Code: 07709374001
For more information on the VENTANA PD-L1 (SP142) Assay, see page 91.

Right therapy, for the right patient, at the right time

By helping identify patients that are more likely to benefit from a specific therapy, complementary diagnostics aid in the choice of specific therapies for each patient.
Primary Antibodies

Breadth

A vast product portfolio supported by the resources and global reach of a leading healthcare company
Ready-to-Use Primary Antibodies

More than 250 prediluted antibodies, optimized for use on VENTANA staining platforms

Featuring a world-class breast panel as well as cornerstone and emerging markers for lung diagnostics and other disease states, our comprehensive portfolio of high-value assays empowers pathology labs to deliver accurate, timely results with clinical confidence.

- **Improve testing efficiency:** Our prediluted antibodies are optimized for use on the fully automated VENTANA BenchMark staining platforms, reducing time-to-result and the resources required with manual or semi-automated solutions.

- **Count on consistent performance:** Roche antibodies have consistently demonstrated (via in-house validation) superior performance when compared to concentrated antibodies that require manual dilution.¹

- **Choose from a comprehensive portfolio:** We offer more than 250 ready-to-use Class I assays, including the largest menu of rabbit monoclonal IVD antibodies available.

<table>
<thead>
<tr>
<th>Breast</th>
<th>Lung</th>
<th>Colorectal</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER (SP1)</td>
<td>TTF-1 (SP141)</td>
<td>MLH-1 (M1)</td>
</tr>
<tr>
<td>PR (1E2)</td>
<td>Cytokeratin 5/6 (D5/16B4)</td>
<td>MSH2 (G219-1129)</td>
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<tr>
<td>HER-2/neu (4B6)</td>
<td>Napsin A (MRQ-60)</td>
<td>MSH6 (44)</td>
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<tr>
<td>Ki-67 (30-9)</td>
<td>p40 (BC28)</td>
<td>PMS2 (EPR3947)</td>
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<td>p53 (DO-7)</td>
<td></td>
<td>BRAF-V600E (VE1)</td>
</tr>
<tr>
<td>HER2 Dual ISH</td>
<td></td>
<td>CDX-2 (EPR2764Y)</td>
</tr>
</tbody>
</table>

Our broad portfolio includes sensitive, specific assays for key markers. Turn the page for a complete listing of our primary antibodies and other IHC/ISH reagents by disease state.
The rabbit monoclonal difference

Superior sensitivity and specificity for consistent, high-quality staining

Demonstrating a better signal-to-noise ratio compared to mouse monoclonal and rabbit polyclonal antibodies,\(^2\) rabbit monoclonals:

- Target a specific epitope
- Provide greater diagnostic specificity
- Reduce background for cleaner slides
- Provide greater consistency from lot to lot

References:


Steering Leslie’s therapy in the right direction

VENTANA high-medical-value assays provide biomarker analysis information that can help drive targeted treatment for cancer patients. Our assays empower pathology labs to deliver accurate, high-quality results that help clinicians gain insights for diagnosis and treatment decisions. Every cancer patient’s journey is unique. Our advanced diagnostics can lead to personalized treatment that helps give patients like Leslie a fighting chance.
## IHC/ISH Reagents by Disease State

**Extensive menu of ready-to-use clinical reagents, optimized for use on VENTANA BenchMark IHC/ISH staining platforms**

### Breast

**Typical Breast Panel Assays**

<table>
<thead>
<tr>
<th>Antibody Name</th>
<th>Source</th>
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</thead>
<tbody>
<tr>
<td>Estrogen Receptor (ER) (SP1), CONFIRM</td>
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</tr>
<tr>
<td>HER-2/neu (4B5), PATHWAY</td>
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</tr>
<tr>
<td>HER2 Dual ISH DNA Probe Cocktail, INFORM</td>
<td></td>
</tr>
<tr>
<td>Ki-67 (30–9), CONFIRM</td>
<td></td>
</tr>
<tr>
<td>p53 (DO-7), CONFIRM</td>
<td></td>
</tr>
<tr>
<td>Progesterone Receptor (PR) (1E2), CONFIRM</td>
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</table>

### Colorectal and Gastrointestinal

**Typical Colorectal Panel Assays**

<table>
<thead>
<tr>
<th>Antibody Name</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAF-V600E (VE1)</td>
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<tr>
<td>CDX-2 (EPR2764Y)</td>
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</tr>
<tr>
<td>MLH-1 (M1)</td>
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</tr>
<tr>
<td>MSH2 (G219-1129)</td>
<td></td>
</tr>
<tr>
<td>MSH6 (44), CONFIRM</td>
<td></td>
</tr>
<tr>
<td>PMS2 (EPR3947)</td>
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</table>

### Dermatopathology

**Typical Melanoma Panel Assays**

<table>
<thead>
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<th>Antibody Name</th>
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<tbody>
<tr>
<td>MART-1/melan A (A103), CONFIRM</td>
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<tr>
<td>Melanoma Associated Antigen (KBA62)</td>
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<tr>
<td>Melanoma Associated Antigen (PNL2)</td>
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<tr>
<td>Melanosome (HMB45), CONFIRM</td>
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<tr>
<td>MITF (C5/D5), CONFIRM</td>
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<tr>
<td>Si00 (Ac4.9), CONFIRM</td>
<td></td>
</tr>
<tr>
<td>Si00 (Polyclonal), CONFIRM</td>
<td></td>
</tr>
<tr>
<td>SOX-10 (SP267)</td>
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</tbody>
</table>

### General Antibodies

<table>
<thead>
<tr>
<th>Antibody Name</th>
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<tbody>
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<td>Albumin, FITC</td>
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<tr>
<td>a-1-Antichymotrypsin (ACT)</td>
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<tr>
<td>a-1-Antitrypsin (AAT)</td>
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<tr>
<td>CEA (TF3H8-1)</td>
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<tr>
<td>CD2 (MRQ-11)</td>
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<tr>
<td>Calponin-1 (EP708Y)</td>
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<tr>
<td>Cytokeratin 14 (SP53)</td>
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<tr>
<td>Cytokeratin 5/6 (D5/16B4)</td>
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<td>Cytokeratin 5/14 (EP1601Y/LL002)</td>
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<td>E-cadherin (36), CONFIRM</td>
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<td>E-cadherin (EP700Y)</td>
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<td>FOXA1 (2F83)</td>
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<td>GATA3 (L50-823)</td>
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<td>GCDFP-15 (EP1582Y)</td>
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<td>p120 (98)</td>
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<td>Topoisomerase Ila (JS5B4), CONFIRM</td>
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<td>Beta-catenin (14)</td>
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<td>Cadherin 17 (SP183)</td>
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<td>CEA (TF3H8-1)</td>
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<td>COX-2 (SP21)</td>
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<td>Cytokeratin 7 (SP52), CONFIRM</td>
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<td>Cytokeratin 19 (A53-B/A2.26)</td>
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<td>Cytokeratin 20 (SP33), CONFIRM</td>
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<td>Glutamine Synthetase (GS-6)</td>
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<td>MUC1 (H23)</td>
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<td>MUC2 (MRQ-18)</td>
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<tr>
<td>IgA (Immunoglobulin A)</td>
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<tr>
<td>IgA (Immunoglobulin A), FITC</td>
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<td>IgG (Immunoglobulin G)</td>
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<td>IgM (Immunoglobulin M), FITC</td>
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<td>Macrophage (HAM-56)</td>
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<td>p53 (DO-7), CONFIRM</td>
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<td>Vimentin (V9), CONFIRM</td>
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<td>Vimentin (Vim 3B4), CONFIRM</td>
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The identified typical antibodies and panels listed for disease state stratification are for informational use only and no medical value or intended use claims are being made. For that information, please refer to the specific product package insert.
PRIMARY ANTIBODIES

A-1-Antichymotrypsin (polyclonal)

- **Catalog Number:** 760-2604
- **Ordering Code:** 05267196001
- **Quantity:** 50 tests
- **Controls:** Histiocytic Tumors
- **Clone Name:** Polyclonal
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
Alpha-1-Antichymotrypsin Primary Antibody reacts with histiocytes and histiocytic neoplasms. Its major application is defining the presence of Alpha-1-Antichymotrypsin in histiocytes and tumors derived from them. In eosinophilic granuloma and malignant histiocytosis, the reaction for this marker is heterogeneous in intensity and distribution. In fibrous histiocytomas on the other hand, a diffuse homogeneous reaction may be observed. Acinar tumors of the pancreas and salivary gland may also exhibit Alpha-1-Antichymotrypsin positivity.

A-1-Antitrypsin (polyclonal)

- **Catalog Number:** 760-2605
- **Ordering Code:** 05267200001
- **Quantity:** 50 tests
- **Controls:** Appendix, Lymph Node, Tonsil
- **Clone Name:** Polyclonal
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
The immunohistochemical staining of Alpha-1-Antitrypsin is considered to be very useful in the study of inherited AAT deficiency, benign and malignant hepatic tumors and yolk sac carcinomas. Positive staining for A-1-Antitrypsin may also be used in detection of benign and malignant lesions of an histiocytic nature. Sensitivity and specificity of the results have made this antibody a useful tool in the screening of patients with cryptogenic cirrhosis or other forms of liver disease with portal fibrosis of uncertain etiology.

ACTH (polyclonal)

- **Catalog Number:** 760-2708
- **Ordering Code:** 05268176001
- **Quantity:** 50 tests
- **Controls:** Normal Pituitary
- **Clone Name:** Polyclonal
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
Anti-ACTH is a useful marker in classification of pituitary tumors and the study of pituitary disease. It reacts with ACTH-producing cells (corticotrophs). It also may react with other tumors (e.g., some small cell carcinomas of the lung) causing paraneoplastic syndromes by secreting ACTH.

Actin, Muscle Specific (HHF35)

- **Catalog Number:** 760-2601
- **Ordering Code:** 05267161001
- **Quantity:** 50 tests
- **Controls:** Skeletal Muscle
- **Isotypes:** IgG 1 /K
- **Clone Name:** HHF35
- **Species:** Mouse
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
Actin is a major component of the cytoskeleton. This antibody recognizes actin of skeletal, cardiac, and smooth muscle cells. It is not reactive with other mesenchymal cells except for myoepithelium. Actin can be resolved on the basis of its isoelectric points into three distinctive components: alpha, beta, and gamma in order of increasing isoelectric point. Anti-Muscle-Specific Actin recognizes alpha and gamma isotypes of all muscle groups. Non-muscle cells such as vascular endothelial cells and connective tissues are non-reactive. Also, neoplastic cells of non-muscle-derived tissue such as carcinomas, melanomas, and lymphomas are negative. This antibody is useful in the identification of rhabdoid cellular elements.
**Actin, Smooth Muscle (1A4) Mouse Monoclonal Antibody**

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<td>Clone Name:</td>
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<td>Cytoplasmic</td>
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<tr>
<td>Regulatory Status:</td>
<td>IVD</td>
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</table>

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Actin, Smooth Muscle (1A4) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification and diagnosis of smooth muscle and myoepithelial tumors within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**anti-Actin, Muscle (HUC1-1) Primary Antibody**

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</table>

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) anti-Actin, Muscle (HUC 1-1) may be used to aid in the identification of cells of normal and abnormal myocytic lineage as an aid in diagnosis of anaplastic tumors. Anti-Actin, Muscle (HUC 1-1) specifically binds to antigens located in the cytoplasm of myocytic cells. This antibody is intended for laboratory use to qualitatively identify by light microscopy muscle actin in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

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**VENTANA ALK (D5F3) CDx Assay**

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**INTENDED USE**

VENTANA ALK (D5F3) CDx Assay is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained with a BenchMark XT or BenchMark ULTRA automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.
### CONFIRM anti-ALK1 (ALK01) Primary Antibody

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-ALK1 (ALK01) Primary Antibody is a mouse monoclonal antibody directed against p80 protein present in human tissue. This antibody is intended for laboratory use to qualitatively stain sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

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### Alpha-Fetoprotein Rabbit Polyclonal Antibody

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Alpha-Fetoprotein (Polyclonal) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of liver disease, yolk sac and mixed germ cell tumors within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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### anti-Androgen Receptor (SP107) Rabbit Monoclonal Primary Antibody

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Androgen Receptor (SP107) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. This antibody is used as an aid in the identification of Androgen Receptor positivity in human tissues within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
INTENDED USE

ANXA1 is strongly expressed on the cell membrane and occasionally in the cytoplasm of tumor cells in 97% of samples from patients with hairy cell leukemia. By contrast, B-cell lymphomas other than hairy cell leukemia, including typical splenic lymphoma with villous lymphocytes and patients with variant hairy cell leukemia—as defined by current morphologic, phenotypic, and clinical criteria—are ANXA1-negative. In a study by Falini et al., ANXA1 immunodetection was 100% sensitive and specific for hairy cell leukemia. Normal B cells from different lympho-hemopoietic tissues were ANXA1-negative. In this study the expression of ANXA1 in myeloid cells, macrophages, or T-cell subset served as positive control. These findings validated the results of gene expression profiling in hairy cell leukemia at the protein level by showing that ANXA1 is consistently expressed in this type of leukemic disease, but not in other B-cell lymphomas. Of note is that negativity for ANXA1 was also present in patients with splenic lymphoma with villous lymphocytes, variant hairy cell leukemia, prolymphocytic leukemia, marginal zone and lymphoplasmacytoid lymphomas. Wang et al. showed that high ANXA1 expression is frequent in esophageal and esophagogastric junction adenocarcinomas, is associated with more advanced pathologic T stage and the presence of distant metastasis, and is an independent prognostic factor for patient survival.

Associated products: TRAcP, T-bet.

anti-S100P (16/f5) Mouse Monoclonal Primary Antibody

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque S100P (16/f5) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification and diagnosis of pancreatic ductal adenocarcinoma and urinary carcinoma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

anti-Arginase-1 (SP156), Rabbit Monoclonal Primary Antibody

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Arginase-1 (SP156) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification and differentiation of hepatocellular carcinoma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
VENTANA Basal Cell Cocktail (34βE12+p63)

Catalog Number: 790-4536 790-1010
Ordering Code: 06364497001 06419445001
Quantity: 50 tests 250 tests
Controls: Normal Basal Cells in Prostate Tissue
Isotypes: IgG2a /K
Clone Name: 34βE12 + 4A4
Species: Mouse
Localization: Nuclear (4A4), Cytoplasmic (34βE12)
Regulatory Status: IVD

INTENDED USE
VENTANA Basal Cell Cocktail (34βE12+p63) is an antibody cocktail of anti-p63 (4A4) and anti-keratin (34βE12). Anti-p63 (4A4) reacts with the p63 molecule in the nuclei of human prostatic basal cells and urothelial tissues. Anti-keratin (34βE12) reacts with cytokeratins 1, 5, 10 and 14, and stains the cytoplasm of human prostatic basal cells. This antibody cocktail may be used to aid in the differentiation of benign and malignant prostatic lesions. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

BCA-225 (Cu-18)

Catalog Number: 760-2607
Ordering Code: 05267226001
Quantity: 50 tests
Controls: Breast Carcinoma
Isotypes: IgG1
Clone Name: Cu-18
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Anti-BCA-225 antibody recognizes a human breast carcinoma associated glycoprotein BCA-225 (220-225kD). This protein differs in size and distribution from other breast carcinoma antigens. Unlike other antibodies against breast carcinoma antigens, this antibody does not react with benign or malignant colonic, stomach, prostate, liver, pancreas, thyroid, or parotid tissues. Adenocarcinomas of the lung, ovary and endometrium also stain with this antibody.

CONFIRM anti-bcl-2 (124) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4464
Ordering Code: 05986826001
Quantity: 50 tests
Controls: Interfollicular T Cells in Tonsil, B Cells of the Mantle Zone
Isotypes: IgG1
Clone Name: 124
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems’ (Ventana) CONFIRM anti-bcl-2 (124) Mouse Monoclonal Primary Antibody (CONFIRM anti-bcl-2 (124)) is directed against human bcl-2 expressed by B cells of the mantle zone and interfollicular T cells. This antibody exhibits a cytoplasmic staining pattern and may be used to aid in the identification of follicular lymphomas and diffuse large cell lymphomas, and to differentiate follicular lymphomas from reactive lymph nodes. CONFIRM anti-bcl-2 (124) is designed to qualitatively detect the presence of cells expressing bcl-2 protein via light microscopy in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
PRIMARY ANTIBODIES

**anti-bcl-2 (SP66) Rabbit Monoclonal Primary Antibody**

- **Catalog Number:** 790-4604
- **Ordering Code:** 06446329001
- **Quantity:** 50 tests
- **Controls:** Interfollicular T Cells in Tonsil, B Cells of the Mantle Zone
- **Clone Name:** SP66
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

Anti-bcl-2 (SP66) Rabbit Monoclonal Primary Antibody is directed against human bcl-2 expressed by B-cells of the mantle zone and interfollicular T cells. This antibody exhibits a cytoplasmic staining pattern and may be used to aid in the identification of follicular lymphomas and diffuse large cell lymphomas. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

**bcl-6 (GI191E/A8)**

- **Catalog Number:** 760-4241
- **Ordering Code:** 05269008001
- **Quantity:** 50 tests
- **Controls:** Lymph Node, Tonsil
- **Isotypes:** IgG1
- **Clone Name:** GI191E/A8
- **Species:** Mouse
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**

Anti-bcl-6 (GI191E/A8) Mouse Monoclonal Antibody is intended for laboratory use in the detection of the bcl6 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

**Beta-Catenin (14)**

- **Catalog Number:** 760-4242
- **Ordering Code:** 05269016001
- **Quantity:** 50 tests
- **Controls:** Fibromatosis of Breast or Abdomen
- **Isotypes:** IgG1
- **Clone Name:** 14
- **Species:** Mouse
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**

Beta-Catenin is a 92 kD protein normally found in the cytoplasm of the cell in the submembranous location. This protein is associated with E-Cadherin and may be essential for the function of E-Cadherin. Mutations in the Beta-Catenin gene result in nuclear accumulation of this protein. Nuclear accumulation of this protein has been demonstrated in fibromatosis lesions of the breast, and abdomen and therefore is useful in differentiating this lesion from other spindle cell lesions that may occur in these locations. Nuclear accumulation of Beta-Catenin has also been demonstrated in colorectal carcinoma.
BG8, Lewis\(^y\) (F3)

**Catalog Number:** 760-4450  
**Ordering Code:** 05973767001  
**Quantity:** 50 tests  
**Controls:** Lung Adenocarcinoma  
**Isotypes:** IgG\(_1\)  
**Clone Name:** F3  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD  

**INTENDED USE**

Blood group antigens have been examined as potential discriminators between pulmonary adenocarcinoma (PACA) and epithelioid mesotheloma (EM). Lewis\(^y\) is the only one of these that appears to have some merit. BG8 is raised from the SK-LU-3 lung cancer line and its ability to distinguish between PACA and EM was first reported by Jordon and colleagues in 1989. Three groups have since reported their results. These studies included 231 cases of PACA and 197 cases of EM. Sensitivity and specificity for PACA were both 93%. Yaziji H et al. reported a sensitivity of nonmesothelial antigens for adenocarcinoma as organ dependent, with BG8 performing at 98% in the breast cancer group, and 100% in the lung cancer group. The specificity of the nonmesothelial (non-EM) antigens for adenocarcinoma was 98% for BG8. They concluded using logical regression analysis that a three-antibody immunohistochemical panel including calretinin, BG8, and MOC-31 would provide 96% sensitivity and specificity for distinguishing EM from adenocarcinoma from a variety of sources (lung, ovary, breast, stomach).

BOB.1 (SP92)

**Catalog Number:** 760-4593  
**Ordering Code:** 06433980001  
**Quantity:** 50 tests  
**Controls:** Tonsil  
**Clone Name:** SP92  
**Species:** Rabbit Monoclonal  
**Localization:** Nuclear, Cytoplasmic  
**Regulatory Status:** IVD  

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque BOB.1 (SP92) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification of B-cells in germinal centers, mantle cells, and differentiation of lymphomas within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.

anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody

**Catalog Number:** 790-4855  
**Ordering Code:** 06918727001  
**Quantity:** 50 tests  
**Controls:** Appropriate positive tissue controls include colorectal adenocarcinoma or thyroid papillary carcinoma with the BRAF V600E mutation  
**Isotypes:** IgG\(_{2a}\)  
**Clone Name:** VE1  
**Species:** Mouse monoclonal antibody  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD  

**INTENDED USE**

Anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody (antiBRAF V600E (VE1)) may be used to aid in the identification of the mutant protein, BRAF V600E. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use.

Ventana Medical Systems’ PATHWAY Anti-c-KIT (9.7) Primary Antibody is intended for laboratory use, via light microscopy, for the qualitative detection of KIT protein in formalin-fixed, paraffin-embedded gastrointestinal stromal tumors (GISTs) using either an automated immunohistochemistry staining system or a manual assay. It is indicated as an aid in the diagnosis of GIST within the context of the patient's clinical history, tumor morphology, and other diagnostic tests evaluated by a qualified pathologist. It may be used after the diagnosis of GIST as an aid in the selection of GIST patients who may qualify for imatinib mesylate (Gleevec/Glivec) therapy.

PATHWAY Anti-c-KIT (9.7) Primary Antibody is optimized for use on Ventana Automated Slide Stainer and for manual application in combination with Ventana Medical Systems’ iVIEW™ DAB Detection Kit and accessories. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

Note: The test is not intended as the sole basis for making the diagnosis of GIST and is not intended as the sole basis for selecting Gleevec/Glivec therapy. The proportion of c-KIT negative GIST patients who can respond to Gleevec/Glivec has not been established. A negative result would not necessarily exclude the diagnosis of GIST, nor should it preclude treatment with Gleevec/Glivec.

All of the subjects in the Novartis Gleevec/Glivec clinical trials were selected using an investigational immunocytochemical antibody (ICA). None of the subjects in those trials were selected using the Ventana PATHWAY Anti-c-KIT (9.7) Primary Antibody. The Ventana PATHWAY Anti-c-KIT (9.7) Primary Antibody was compared to the ICA on independent sets of samples and found to provide acceptably concordant results.


INTENDED USE

Anti-c-MYC (Y69) Rabbit Monoclonal Primary Antibody (anti-c-MYC (Y69)) is directed against the transcription factor c-MYC, an important factor in cell cycle regulation. The anti-c-MYC (Y69) antibody exhibits a nuclear staining pattern and may be used to aid in the characterization of lymphoma. This antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
**C3d Rabbit Polyclonal Antibody**

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**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque anti-C3d (polyclonal) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using VENTANA BenchMark automated IHC test methods. Use of this antibody is indicated as an aid in the identification of C3d and the diagnostic determination of acute kidney rejection within the context of the patient's clinical history and other diagnostic tests evaluated by a qualified pathologist or physician.

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**C4d (polyclonal)**

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**INTENDED USE**
C4d is a stable split product remnant of classical complement activation which becomes covalently bound to endothelium and basement membrane, after induction of the classical antibody-induced pathway. As an established marker of antibody-mediated acute renal allograft rejection and its proclivity for endothelium, this component can be detected in peritubular capillaries in both chronic renal allograft rejection as well as hyperacute rejection, acute vascular rejection, acute cellular rejection, and borderline rejection. It has been shown to be a significant predictor of transplant kidney graft survival and is an aid in treating acute rejection.

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**C4d (SP91)**

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**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque C4d (SP91) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification and differentiation of C4d within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
## CA-125 (OC125)

**Catalog Number:** 760-2610  
**Ordering Code:** 05267269001  
**Quantity:** 50 tests  
**Controls:** Ovarian Carcinoma  
**Isotypes:** IgG/K  
**Clone Name:** OC125  
**Species:** Mouse  
**Localization:** Membranous, Cytoplasmic  
**Regulatory Status:** IVD

### INTENDED USE
Anti-CA 125 (OC125) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CA 125 protein in formalin-fixed, paraffin-embedded neoplastic tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

## CA19-9 (121SLE)

**Catalog Number:** 760-2609  
**Ordering Code:** 05267242001  
**Quantity:** 50 tests  
**Controls:** Colon, Salivary Gland  
**Isotypes:** IgM  
**Clone Name:** 121SLE  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

### INTENDED USE
CA19-9 antigen is highly expressed in gastrointestinal (gastric, pancreatic, and colonic) adenocarcinomas and salivary gland mucoepidermoid carcinomas. Anti-CA19-9 antibody is usually not reactive with breast, kidney, and prostate carcinomas.

## Cadherin 17 (SP183) Rabbit Monoclonal Primary Antibody

**Catalog Number:** 760-4865  
**Ordering Code:** 07047703001  
**Quantity:** 50 tests  
**Controls:** Colorectal Carcinoma  
**Isotypes:** IgG  
**Clone Name:** SP183  
**Species:** Rabbit Monoclonal  
**Localization:** Membranous, Cytoplasmic  
**Regulatory Status:** IVD

### INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Cadherin 17 (SP183) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of gastrointestinal carcinoma within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.
### Calcitonin (polyclonal)

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**INTENDED USE**

Immunohistochemical staining with anti-calcitonin antibody has proven to be an effective way of demonstrating calcitonin-producing cells in the thyroid. C-cell hyperplasia and medullary thyroid carcinomas stain positive for calcitonin. Studies of calcitonin have resulted in the identification of a wide spectrum of C-cell proliferative abnormalities.

### anti-Calcitonin (SP17), Rabbit Monoclonal Primary Antibody

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<td>Regulatory Status:</td>
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</tbody>
</table>

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Calcitonin (SP17) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. This antibody is used as an aid in the identification of thyroid C-cells and diagnosis of thyroid medullary carcinoma within the context of an antibody panel, patient's clinical history, and other diagnostic tests determined by a qualified pathologist.

### Caldesmon (E89)

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<td>Clone Name:</td>
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<td>Regulatory Status:</td>
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</table>

**INTENDED USE**

Anti-Caldesmon is a regulatory protein found in smooth muscle and other tissues which interacts with actin, myosin, tropomyosin, and calmodulin. Anti-Caldesmon antibody labels smooth muscle and tumors of smooth muscle, myofibroblast, and myoepithelial differentiation. Anti-Caldesmon has also been used to differentiate epithelioid mesothelioma from serous papillary carcinoma of the ovary.
**Calponin-1 (EP798Y)**

**Catalog Number:** 760-4376  
**Ordering Code:** 05435684001  
**Quantity:** 50 tests  
**Controls:** Esophagus, Smooth Muscle from Bowel, Uterus  
**Isotypes:** IgG  
**Clone Name:** EP798Y  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Calponin-1 (EP798Y) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of smooth muscle cell tumors within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**CONFIRM Calretinin (SP65) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 790-4467  
**Ordering Code:** 05992184001  
**Quantity:** 50 tests  
**Controls:** Mesothelioma, Normal Appendix  
**Clone Name:** SP65  
**Species:** Rabbit  
**Localization:** Cytoplasmic, Nuclear  
**Regulatory Status:** IVD

**INTENDED USE**

Ventana Medical Systems’ (Ventana) CONFIRM anti-Calretinin (SP65) Rabbit Monoclonal Primary Antibody (CONFIRM anti-Calretinin (SP65)) is directed against the calcium binding protein, calretinin, expressed by normal and reactive mesothelium, eccrine glands of skin, Sertoli cells of the testis, ovarian stromal cells and adrenal cortical cells. This antibody exhibits a nuclear and cytoplasmic staining pattern and may be used to aid in the identification of mesothelioma, and in distinguishing mesothelioma from adenocarcinoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

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**Caveolin-1 (SP43) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 760-4951  
**Ordering Code:** 07391439001  
**Quantity:** 50 tests  
**Controls:** Ewings Sarcoma, Mesothelioma  
**Isotypes:** IgG  
**Clone Name:** SP43  
**Species:** Rabbit  
**Localization:** Membranous  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Caveolin-1 (SP43) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the differentiation of mesothelioma and Ewing sarcoma from other tumors within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.
CD1a (EP3622)

**Intended Use**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD1a (EP3622) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of lymphoblastic lymphoma/leukemia and Langerhans cell histiocytosis within the context of antibody panels, the patient’s clinical history and other diagnostic tests evaluated by a qualified pathologist.

CD2 (MRQ-11)

**Intended Use**
Human T lymphocytes were initially distinguished from B lymphocytes by their ability to produce spontaneous rosettes with sheep red blood cells, a phenomenon mediated by the CD2 molecule, a glycosylated transmembrane receptor molecule also referred to as T11 antigen or LFA-3 antigen (leukocyte function associated antigen -3). Three functionally important epitope groups have been defined on the humans CD2 molecule, designated T111, T112, and T113, (CD2R). T111, is the epitope responsible for E-rosetting and T cell stimulation through this epitope and is mediated by an IL-2 dependent pathway (Meur et al, 1984; Knowles, 1984). Stimulation of the T112 and T113 epitopes occurs via an alternative pathway (Meur et al, 1984; Knowles, 1984).

CD2 is one of the earliest T cell lineage restricted antigens to appear during T cell differentiation and only a rare CD2+ cell can be found in the bone arrow. It is found in all T-lymphocytes and natural killer cells but not in B cells or any other cell population. CD2 binds to its counter receptor CD-58 (LFA-3), a member of the Ig gene superfamily, which located on the surface of target cells. CD2 binding to LFA-3 activates T cells and may also have a role in prothymocyte homing as it is known to mediate thymocyte-thymic epithelium adhesion. Although it is known that CD2 appears after CD7 but before CD1, its temporal relationship with CD3 is less definite, with some recent evidence suggesting that CD3 appears in the cytoplasm before CD2 (Osborn et al, 1995).

CD2 can be considered a pan-T cell antigen and is therefore useful for the identification of virtually all normal T lymphocytes. It is also very useful in the assessment of lymphoid malignancies as it is expressed in the majority of precursor and post-thymic lymphomas and leukemias and is not expressed by B neoplasms (Foon & Todd, 1986). As with other pan-T cell antigens, CD2 may be aberrantly deleted in some neoplastic T cell population, especially peripheral T cell lymphomas. Rarely slg+ B cell neoplasms have been described to form spontaneous E-rosettes but these reactions are not mediated via the CD2 receptor (Knowles, 1989).

CONFIRM anti-CD3 (2GV6) Rabbit Monoclonal Primary Antibody

**Intended Use**
Ventana Medical Systems, Inc.’s (Ventana) CONFIRM anti-CD3 (2GV6) (Primary Antibody (CONFIRM anti-CD3 (2GV6)) is a rabbit monoclonal antibody (IgG) directed against the nonglycosylated epsilon chain of the human CD3 molecule. This antibody is intended for use to qualitatively identify T cells by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
CONFIRM anti-CD4 (SP35) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4423  
Ordering Code: 05552737001  
Quantity: 50 tests  
Controls: Liver, Tonsil  
Clone Name: SP35  
Species: Rabbit  
Localization: Membranous  
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-CD4 (SP35) Rabbit Monoclonal Primary Antibody is intended for the qualitative detection of CD4 in sections of formalin-fixed, paraffin-embedded normal and neoplastic human tissues. CD4 is present on helper-inducer T lymphocytes that recognize antigen in the context of MHC class 2 molecules. CD4 positive staining results may aid in identifying T-cell lymphomas and in identifying the T helper-inducer cell subset of T lymphocytes in normal tissues. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4451  
Ordering Code: 05929903001  
Quantity: 50 tests  
Controls: Tonsil, Lymphoma  
Clone Name: SP19  
Species: Rabbit  
Localization: Cell Membrane, Cytoplasmic  
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems’ (Ventana) CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody is directed against human CD5 expressed on the plasma membrane of virtually all human T cells and the B1a subset of human B cells found in the follicular mantle zones, bone marrow and peripheral blood. Staining CD5 is commonly used as part of several IHC panels to determine T cell and B cell subclassifications. CD5 may be used to aid in the identification of T cell lymphomas, and certain B cell lymphomas, including mantle cell lymphoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

anti-CD7 (SP94) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4558  
Ordering Code: 06537847001  
Quantity: 50 tests  
Controls: Thymus, Tonsil  
Isotypes: Rabbit Ig  
Clone Name: SP94  
Species: Rabbit  
Localization: Membranous  
Regulatory Status: IVD

INTENDED USE
Anti-CD7 (SP94) Rabbit Monoclonal Primary Antibody (anti-CD7 (SP94)) is directed against the 40kD transmembrane glycoprotein, CD7 which is present in thymocytes and mature T cells. Anti-CD7 (SP94) may be used to aid in the identification of T cell lymphomas. This antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
CONFIRM anti-CD8 (SP57) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4460  
Ordering Code: 05937248001  
Quantity: 50 tests  
Controls: Tonsil, T Cell Lymphoma  
Clone Name: SP57  
Species: Rabbit  
Localization: Cell Membrane  
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems’ (Ventana) CONFIRM anti-CD8 (SP57) Rabbit Monoclonal Primary Antibody (CONFIRM anti-CD8 (SP57)) is intended for the qualitative detection of CD8 in sections of normal and neoplastic human tissues. The CD8 glycoprotein is present on cytotoxic/suppressor T lymphocytes that recognize antigen in the context of MHC class 1 molecules. CD8 positive staining results may aid in identifying T-cell lymphomas and in identifying the T cytotoxic/suppressor cell subset of T lymphocytes in normal tissues. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

VENTANA anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4506  
Ordering Code: 05857856001  
Quantity: 50 tests  
Controls: Tonsil  
Isotypes: Rabbit Ig  
Clone Name: SP67  
Species: Rabbit  
Localization: Membranous, Cytoplasmic  
Regulatory Status: IVD

INTENDED USE
VENTANA anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody is directed against the CD10 molecule, or common acute lymphoblastic leukemia antigen (CALLA), expressed on the surface of early lymphoid cells, and on various nonlymphoid tissues including breast myoepithelial cells, bile canaliculi, fibroblasts, kidney tubular brush borders and small intestine epithelium. This antibody exhibits a cell membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of Burkitt’s lymphoma and follicular germ cell lymphoma, and in the classification of some carcinomas such as renal cell carcinoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

CD13 (SP187) Rabbit Monoclonal Primary Antibody

Catalog Number: 760-4862  
Ordering Code: 07047673001  
Quantity: 50 tests  
Controls: Liver  
Isotypes: IgG  
Clone Name: SP187  
Species: Rabbit Monoclonal  
Localization: Cytoplasmic, Membranous  
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD13 (SP187) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification of acute myeloid leukemia and hepatocellular carcinomas within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.
CD14 (EPR3653) Rabbit Monoclonal Antibody

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD14 (EPR3653) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification and diagnosis of myeloid leukemia and histiocytic neoplasms within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

CONFIRM anti-CD15 (MMA) Mouse Monoclonal Primary Antibody

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**INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems’ CONFIRM anti-CD15 (MMA) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody (IgM, kappa) directed against a carbohydrate epitope present on most granulocytic cells. This antibody is intended for use to qualitatively identify CD15 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on the Ventana automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.


CD16 (SP175) Rabbit Monoclonal Primary Antibody

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD16 (SP175) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification of lymphomas and leukemias in the tissue within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
CONFIRM anti-CD20 (L26) Primary Antibody

Catalog Number: 760-2531
Ordering Code: 05267099001
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG2a/K
Clone Name: L26
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-CD20 (L26) Primary Antibody is a mouse monoclonal antibody (IgG2a, kappa) directed against an epitope present on human B lymphocytes. This antibody is intended for use to qualitatively identify cells of B lymphocytic lineage1 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.


CD21 (2G9)

Catalog Number: 760-4245
Ordering Code: 05269059001
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG2a
Clone Name: 2G9
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

INTENDED USE

Anti-CD21 Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD21 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

CD21 (EP3093)

Catalog Number: 760-4438
Ordering Code: 05973902001
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG1
Clone Name: EP3093
Species: Rabbit
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

INTENDED USE

CD21 antigen is an integral membrane glycoprotein of molecular weight 140 kD. Anti-CD21 is useful in the identification of follicular dendritic cell matrix found in normal lymph nodes and tonsillar tissue. This antibody also labels follicular dendritic cell tumor/sarcomas. The antigen is absent on T-lymphocytes, monocytes, and granulocytes.

Associated products: CD35, Follicular Dendritic Cell
anti-CD22 (SP104) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4588  
Ordering Code: 06391117001  
Quantity: 50 tests  
Controls: Tonsil  
Clone Name: SP104  
Species: Rabbit Monoclonal  
Localization: Membranous, Cytoplasmic  
Regulatory Status: IVD

INTENDED USE

Anti-CD22 (SP104) Rabbit Monoclonal Primary Antibody (antiCD22 (SP104)) is directed against the type 1 integral membrane glycoprotein, CD22. Anti-CD22 (SP104) exhibits a cell membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of B-cell lymphomas. This antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

CONFIRM anti-CD23 (SP23) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4408  
Ordering Code: 05479258001  
Quantity: 50 tests  
Controls: Tonsil  
Clone Name: SP23  
Species: Rabbit  
Localization: Cytoplasmic  
Regulatory Status: IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM antiCD23 (SP23) Rabbit Monoclonal Primary Antibody is designed to qualitatively detect the presence of CD23 expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue. Positive staining may be useful in classifying small lymphocytic lymphoma/leukemia from other small B-cell lymphomas including mantle cell and marginal zone lymphoma. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

CD25 (4C9)

Catalog Number: 760-4439  
Ordering Code: 05973899001  
Quantity: 50 tests  
Controls: Lesions of Mastocytosis, Small Bowel  
Isotypes: IgG2b  
Clone Name: 4C9  
Species: Mouse  
Localization: Cytoplasmic, Membranous  
Regulatory Status: IVD

INTENDED USE

According to the World Health Organization classification system, the major diagnostic criterion for bone marrow involvement by Systemic Mastocytosis (SM) is the presence of dense aggregates (>15 cells) of mast cells. Expression of CD25, a low-affinity receptor for interleukin-2 (IL-2), is a reliable diagnostic tool for distinguishing neoplastic mast cell aggregates from reactive proliferations, and has therefore recently become a minor criterion for the diagnosis of SM. Hahn et al. demonstrated that aberrant staining of Mast cell clusters by anti-CD25 antibody in GI biopsies was essentially diagnostic of SM. Anti-CD25 antibody has also been useful in identifying mast cells in skin biopsies in the setting of Urticaria Pigmentosa, which is predictive of Systemic Mastocytosis. Quantitation of regulatory T cells (Treg) in the setting of hepatocellular carcinoma has been used as an independent predictive factor of tumor recurrence after hepatic resection for HCC. Also, the percentage of tumor-infiltrating CD25+FOXP3+ regulatory T cells among tumor cells, inside tumor parenchyma and at its periphery, is significantly higher in recurrent cutaneous melanoma than in non-recurrent melanoma.
**anti-CD30 (Ber-H2) Mouse Monoclonal Primary Antibody**

**Catalog Number:** 790-4858  
**Ordering Code:** 07007841001  
**Quantity:** 50 tests  
**Controls:** Positive control tissue: Lymphoma or Tonsil  
Negative control tissue: Tonsil Germinal Center B-cells  
**Isotypes:** IgG1/K  
**Clone Name:** Ber-H2  
**Species:** Mouse  
**Localization:** Cell Membrane, Cytoplasmic, Golgi  
**Regulatory Status:** IVD  

**INTENDED USE**

The anti-CD30 (Ber-H2) Mouse Monoclonal Primary Antibody (antiCD30 (Ber-H2)) is intended for laboratory use in the detection of the CD30 protein in formalin-fixed, paraffin-embedded tissue stained with a VENTANA BenchMark series immunohistochemical (IHC) automated slide stainer. CD30 positive staining results may aid in the identification of classical Hodgkin lymphoma and anaplastic large cell lymphoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

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**CONFIRM anti-CD30 (Ber-H2) Primary Antibody**

**Catalog Number:** 790-2926  
**Ordering Code:** 05278201001  
**Quantity:** 50 tests  
**Controls:** Hodgkins Lymphoma  
**Isotypes:** IgG1/K  
**Clone Name:** Ber-H2  
**Species:** Mouse  
**Localization:** Membranous  
**Regulatory Status:** IVD  

**INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' CONFIRM anti-CD30 (Ber-H2) Primary Antibody contains a mouse monoclonal antibody (IgG1, kappa) directed against CD30. The antibody is intended for use to qualitatively identify CD30 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a Ventana automated slide staining device. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

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**CD31 (JC70)**

**Catalog Number:** 760-4378  
**Ordering Code:** 05463475001  
**Quantity:** 50 tests  
**Controls:** Appendix, Placenta, Tonsil  
**Isotypes:** IgG1/K  
**Clone Name:** JC70  
**Species:** Mouse  
**Localization:** Cytoplasmic, Membranous  
**Regulatory Status:** IVD  

**INTENDED USE**

Anti-CD31 (JC70) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD31 protein in formalin-fixed, paraffin-embedded neoplastic tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
CD33 (SP266) Rabbit Monoclonal Primary Antibody

**Catalog Number:** 760-4952  
**Ordering Code:** 07391447001  
**Quantity:** 50 tests  
**Controls:** Acute Leukemia, Placenta Syncytiotrophoblasts  
**Isotypes:** IgG  
**Clone Name:** SP266  
**Species:** Rabbit  
**Localization:** Membranous  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD33 (SP266) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of acute leukemia within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

CONFIRM anti-CD34 (QBEnd/10) Primary Antibody

**Catalog Number:** 790-2927  
**Ordering Code:** 05278210001  
**Quantity:** 50 tests  
**Controls:** Appendix, Placenta, Tonsil  
**Isotypes:** IgG  
**Clone Name:** QBEnd/10  
**Species:** Mouse  
**Localization:** Membranous  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-CD34 (QBEnd/10) Primary Antibody is a mouse monoclonal antibody (IgG1) directed against human CD34. This antibody is intended for use to qualitatively identify CD34 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

anti-CD43 (L60) Mouse Monoclonal Primary Antibody

**Catalog Number:** 760-2511  
**Ordering Code:** 05266980001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Tonsil  
**Isotypes:** IgG  
**Clone Name:** L60  
**Species:** Mouse  
**Localization:** Membranous  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) Anti-CD43 (L60) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody directed against an epitope present on human monocytes, granulocytes and lymphocytes. This reagent may be used to aid in the identification of cells of lymphoid and myelomonocytic lineage. Anti-CD43 (L60) is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

**anti-CD44 (SP37) Rabbit Monoclonal Primary Antibody**

- **Catalog Number:** 790-4537
- **Ordering Code:** 08364965001
- **Quantity:** 50 tests
- **Controls:** Normal Tonsil
- **Isotypes:** IgG
- **Clone Name:** SP37
- **Species:** Rabbit
- **Localization:** Membranous
- **Regulatory Status:** IVD

**INTENDED USE**

Anti-CD44 (SP37) Rabbit Monoclonal Primary Antibody is directed against the CD44 protein. CD44 is a type I transmembrane receptor protein expressed in several cell types including T and B lymphocytes, monocytes, granulocytes, erythrocytes, fibroblasts, epithelial, and mast cells. This antibody exhibits a membranous staining pattern and may be used to detect the CD44 standard and variant proteins in a variety of neoplastic tissues, including squamous cell and urothelial carcinoma. The antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

**CD45 (LCA) (2B11 & PD7/26)**

- **Catalog Number:** 760-4279
- **Ordering Code:** 05269423001
- **Quantity:** 50 tests
- **Controls:** Lymph Node, Tonsil
- **Isotypes:** IgG1/K
- **Clone Name:** 2B11 & PD7/26
- **Species:** Mouse
- **Localization:** Membranous
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD45 (LCA) (2B11 & PD7/26) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of lymphoid neoplasms within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

**CONFIRM anti-CD45, LCA (RP2/18) Primary Antibody**

- **Catalog Number:** 760-2505
- **Ordering Code:** 05266912001
- **Quantity:** 50 tests
- **Controls:** Tonsil
- **Isotypes:** IgG1/K
- **Clone Name:** RP2/18
- **Species:** Mouse
- **Localization:** Membranous
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-CD45, LCA (RP2/18) Primary Antibody is a mouse monoclonal antibody (IgG1) directed against CD45. CONFIRM anti-CD45, LCA (RP2/18) may be used in immunocytochemical methods to aid in the identification of normal and abnormal cells of leukocytic lineage and as an aid in the diagnosis of anaplastic tumors. CONFIRM anti-CD45, LCA (RP2/18) specifically binds to antigens located on the membrane of leukocytes. Staining is most consistent for lymphocytic cells with less consistent reaction in other leukocytes (macrophages/histiocytes/myeloid cells). The epitope recognized by the antibody is LCA-RB. CONFIRM anti-CD45, LCA (RP2/18) is intended for laboratory use to qualitatively stain leukocytes in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. Light microscopy is used to detect the staining of cell components. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.
CD45R (MB1)

**Catalog Number:** 760-2624  
**Ordering Code:** 05267340001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Tonsil  
**Isotypes:** IgG1  
**Clone Name:** MB1  
**Species:** Mouse  
**Localization:** Membranous  
**Regulatory Status:** IVD

**INTENDED USE**

MB1 antibody stains preferentially B-cells and their neoplasms but is less specific as it will also react with some T-cell lymphomas and non-lymphoid tumors. The antigen for this antibody is in the membrane of all B-cells with the exception of plasma cells and some mature T-cells.

CONFIRM anti-CD45RO (UCHL-1) Primary Antibody

**Catalog Number:** 790–2930  
**Ordering Code:** 05278244001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Tonsil  
**Isotypes:** IgM  
**Clone Name:** UCHL-1  
**Species:** Mouse  
**Localization:** Membranous  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-CD45RO (UCHL-1) Primary Antibody is a mouse monoclonal antibody (IgG2a) directed against CD45RO. This antibody is intended for use to qualitatively identify CD45RO by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

CONFIRM anti-CD56 (123C3) Mouse Monoclonal Primary Antibody

**Catalog Number:** 790-4465  
**Ordering Code:** 05878519001  
**Quantity:** 50 tests  
**Controls:** Brain, Normal Pancreas  
**Isotypes:** IgG1  
**Clone Name:** 123C3  
**Species:** Mouse  
**Localization:** Membrane, Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

Ventana Medical Systems’ (Ventana) CONFIRM anti-CD56 (123C3) Mouse Monoclonal Primary Antibody (CONFIRM anti-CD56 (123C3)) is directed against the CD56 molecule or neural cell adhesion molecule expressed by most neuroectodermally derived cell lines, tissues and neoplasms. It is also expressed on some mesodermally derived tumors, on natural killer cells, and NK cell lymphomas. This antibody exhibits a membrane/cytoplasmic staining pattern and may be used to aid in the identification of small cell carcinomas, neuroblastoma, and rhabdomyosarcoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
**CD56 (MRQ-42)**

**Catalog Number:** 760-4596  
**Ordering Code:** 0643359001  
**Quantity:** 50 tests  
**Controls:** Pancreatic Islet Cells, Pancreatic Endocrine Cells, Neuroblastoma  
**Clone Name:** MRQ-42  
**Species:** Rabbit Monoclonal  
**Localization:** Cytoplasmic, Membranous  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD56 (MRQ-42) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification of neural/neuroendocrine tissues, natural killer (NK) cells, NK-like T-cells, and diagnosis of related neoplasms within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**CD57 (NK-1)**

**Catalog Number:** 760-2626  
**Ordering Code:** 05267366001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Tonsil  
**Isotypes:** IgM/K  
**Clone Name:** NK-1  
**Species:** Mouse  
**Localization:** Membranous  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD57 (NK-1) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of T-cell large granular lymphocyte disorders, oligodendrogliomas, and neuroendocrine tumors within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**CD61 (2f2)**

**Catalog Number:** 760-4249  
**Ordering Code:** 05269091001  
**Quantity:** 50 tests  
**Controls:** Bone Marrow  
**Isotypes:** IgG  
**Clone Name:** 2f2  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
Antibody to CD61 labels the Il1a sub-unit of the non-covalently linked glycoprotein heterodimer Ilb/Il1a complex present on human platelets and their precursors. This antibody is useful in identifying megakaryoblastic differentiation as seen in megakaryoblastic leukemia.
CD63 (NKI/C3)

**INTENDED USE**
This antibody reacts with a 53 kDa protein which forms a part of the family of tetraspan moieties. The antigen was originally designated as a lysosomal membrane protein characterized as an activation dependent platelet surface antigen. In fact the CD63 antigen has a diverse distribution on the surface and in the cytoplasm of many cell types including lymphoid, myeloid, endothelial cells and melanoma. It has been quite useful in identifying malignant melanoma. Mete et al. found it useful in differentiating renal oncocytomas (RO) from eosinophilic renal cell carcinomas (eRCC). In his series of 35 ROs, 94% demonstrated apical and/or polar CD63 positivity. Of his 77 eRCCs, 96% showed diffuse cytoplasmic staining.

CONFIRM anti-CD68 (KP-1) Primary Antibody

**INTENDED USE**
This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' (Ventana®) CONFIRM anti-CD68 (KP-1) Primary Antibody is a mouse monoclonal antibody, class IgG1 kappa. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-CD68 reacts with a 110 KD intracellular glycoprotein associated with the cell membrane of macrophages and some myeloid elements. Unexpected antigen expression or loss of expression may occur, especially in neoplasms. Occasionally stromal elements surrounding heavily stained tissue or cells will show immunoreactivity. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.


CD71 (MRQ-48) Mouse Monoclonal Antibody

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD71 (MRQ-48) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification of the erythroid precursors in bone marrow and in the determination of acute myeloid leukemia and myelodysplastic syndrome (MDS) within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.
CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4432
Ordering Code: 05640296001
Quantity: 50 tests
Controls: Tonsil, B Cell Lymphoma
Clone Name: SP18
Species: Rabbit
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems’ (Ventana) CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody is intended for the detection of CD79a in normal and neoplastic human tissues. AntiCD79a is directed against a protein expressed on the surface of B lymphocytes at all stages of maturation, from B lymphocyte precursors through plasma cells. Expression of CD79a may aid in the identification of B cell lineage in malignant lymphomas. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

CONFIRM anti-CD99 (O13) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4452
Ordering Code: 05913594001
Quantity: 50 tests
Controls: Pancreatic Islet Cells, Sertoli Cells of the Testis
Isotypes: IgG1
Clone Name: O13
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems’ (Ventana) CONFIRM anti-CD99 (O13) Mouse Monoclonal Primary Antibody (CONFIRM anti-CD99 (O13)) is directed against human CD99 expressed on T lymphocytes, cortical thymocytes, granulosa cells of the ovary, pancreatic islet cells, CNS ependymal cells and Sertoli's cells. CD99 shows a plasma membrane location. This antibody may be used as part of a panel to aid in the identification of Ewing's sarcoma and related peripheral neuroectodermal tumors. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

CD138/syndecan-1 (B-A38)

Catalog Number: 760-4248
Ordering Code: 05269083001
Quantity: 50 tests
Controls: Plasmacytoma, Tonsil
Isotypes: IgG
Clone Name: B-A38
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

INTENDED USE
Anti-CD138 Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD138 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
CD163 was recently identified as an acute phase-regulated transmembrane protein whose function is to mediate the endocytosis of haptoglobin-hemoglobin complexes. This receptor is expressed on the surface of monocytes (low expression) and tissue macrophages [also known as histiocytes] (high expression). It is a member of the cysteine-rich scavenger receptor superfamily, encoded by a gene localized on human chromosome 12p13.3. Solubilized in plasma, CD163 functions as an anti-inflammatory signal and has many roles in disease processes that range from autoimmune conditions such as rheumatoid arthritis to atherosclerosis. Previous work has shown that the CD163 gene can be regulated by glucocorticoids, IL-10, and other inflammatory modulators, and is highly expressed in inflamed tissues, consistent with its role in the resolution of inflammation. Staining for CD163 has been helpful in distinguishing synovial macrophages from synovial intimal fibroblasts in the setting of rheumatoid arthritis, where its specificity for macrophages was found to be superior to that of CD68, which does not discriminate between these cell types. Increased levels of CD163 were also detected in patients with microbial infections and myelomonocytic leukemias by an enzyme-linked immunosorbent assay. Flow cytometry studies have confirmed that CD163 expression is limited to leukemias with monocytic differentiation. Another recent study showed that all 5 cases of synovial-type giant cell tumors of the vertebral column stained for CD163.

CDX-2 Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CDX-2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CEA (CEA31) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification and diagnosis of adenocarcinomas within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
**Anti-CEA (TF 3H8-1) Primary Antibody**

**Catalog Number:** 760-2507  
**Ordering Code:** 05266947001  
**Quantity:** 50 tests  
**Controls:** Colon  
**Isotypes:** IgG  
**Clone Name:** TF3H8-1  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems’ (Ventana) CEA (TF 3H8-1) Primary Antibody may be used to aid in the identification of cells of normal and abnormal epithelial lineage as an aid in diagnosis of anaplastic tumors. CEA (TF 3H8-1) Primary Antibody specifically binds to antigens located in the plasma membrane and cytoplasmic regions of normal simple epithelial cells. CEA (TF 3H8-1) is a mouse monoclonal antibody (IgG1) directed against carcinoembryonic antigen (CEA). The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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**anti-Chromogranin A (LK2H10) Primary Antibody**

**Catalog Number:** 760-2519  
**Ordering Code:** 05267056001  
**Quantity:** 50 tests  
**Controls:** Pancreas  
**Isotypes:** IgG1/K  
**Clone Name:** LK2H10  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems’ (Ventana) anti-Chromogranin A (LK2H10) Primary Antibody contains a mouse monoclonal antibody (IgG1) directed against a protein found in the secretory granules of most endocrine cells. The Chromogranin A protein is widely expressed in neuronal tissues and in the secretory granules of human endocrine cells. Chromogranin A is also expressed by adrenal (medulla), parathyroid, anterior pituitary cells, islet cells of the pancreas, gastrointestinal cells, bronchial endocrine cells, and thyroid c-cells. Chromogranin A is expressed in tumors of neuroendocrine origin, including pheochromocytomas, pituitary adenomas, islet cell tumors, medullary thyroid carcinomas, carcinoids and Merkel cell tumors. This reagent may be used to aid in the identification of cells of normal or neoplastic neuroendocrine lineage. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue on a Ventana automated slide stainer. Anti-Chromogranin A (LK2H10) specifically binds to the chromogranin A protein located in the secretory granules of normal and neoplastic neuroendocrine cells. Unexpected antigen expression or loss of expression may occur, especially in neoplasms. Occasionally stromal elements surrounding heavily stained tissue and/or cells will show immunoreactivity. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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**CINtec® Histology Kit**

**Catalog Number:** 9517  
**Ordering Code:** 06594450001  
**Quantity:** 50 tests  
**Controls:** Normal Pancreas, Normal Tonsil, Cervical Carcinoma  
**Isotypes:** IgG<sub>2a</sub>  
**Clone Name:** E6H4™  
**Species:** Mouse monoclonal  
**Regulatory Status:** IVD

**INTENDED USE**

For in vitro diagnostic use. The CINtec® Histology Kit is an immunohistochemistry assay for the qualitative detection of the p16<sup>INK4a</sup> antigen on formalin-fixed, paraffin-embedded tissue sections prepared from cervical biopsies. It is intended for use in medical pathology laboratories to provide adjunctive information after initial diagnosis has been made by established diagnostic methods. Interpretation of the test results may only be made by a certified professional in conjunction with the patient’s clinical history and any additional diagnostic tests that have been performed.
**INTENDED USE**

CINtec p16 Histology is an immunohistochemistry assay for the qualitative detection of the p16INK4a protein on formalin-fixed, paraffin-embedded tissue sections prepared from cervical biopsies. It is intended for use in medical pathology laboratories to provide adjunctive information after initial diagnosis has been made by established diagnostic methods. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

**COX-2 (SP21)**

Cyclooxygenase 2 catalyzes the conversion of arachidonic acid to prostaglandin H2 in the first step in the biosynthesis of prostaglandins, thromboxanes, and prostacyclins. COX-2 inhibition by nonsteroidal antiinflammatory agents has been shown to decrease angiogenesis, and tumor growth, and promote apoptosis. COX-2 overexpression has been associated with increased microvascular density, and VEGF protein expression in head and neck squamous cell carcinoma and is a poor prognostic indicator in this entity as well. COX-2 overexpression has also been suggested as a poor prognostic indicator in carcinomas of the colon, breast, pancreas, and adenocarcinoma of the lung.
VENTANA anti-Cyclin D1 (SP4-R) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4508
Ordering Code: 05862949001
Quantity: 50 tests
Controls: Normal Tonsil
Isotypes: IgG
Clone Name: SP4-R
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE
VENTANA anti-Cyclin D1 (SP4-R) Rabbit Monoclonal Primary Antibody (VENTANA anti-Cyclin D1 (SP4-R)) is directed against the Cyclin D1 molecule, a key cell cycle regulator, expressed primarily during the G1 phase of the cell cycle. This antibody exhibits a nuclear staining pattern, and may be used to aid in the identification of mantle cell lymphoma, and breast carcinoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

Cytokeratin (35betaH11)

Catalog Number: 760-2637
Ordering Code: 05267471001
Quantity: 50 tests
Controls: Prostate
Isotypes: IgM/K
Clone Name: 35betaH11
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Anti-Cytokeratin 8 stains most non-squamous epithelial tumors, squamous tumors are negative for this antibody as a rule. This antibody stains adenocarcinomas of the breast, ovary, gastrointestinal tract, thyroid, pancreas, bile duct, and salivary glands. This antibody does not react with skeletal muscle or nerve cells.

CONFIRM anti-Cytokeratin (AE1) Primary Antibody

Catalog Number: 760-2521
Ordering Code: 05267064001
Quantity: 50 tests
Controls: Prostate, Salivary Gland
Isotypes: IgG1
Clone Name: AE1
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) CONFIRM anti-Cytokeratin (AE1) is intended for laboratory use to qualitatively stain cytokeratin in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-Cytokeratin (AE1) may be used to aid in the identification of cells of normal and abnormal epithelial lineage as an aid in diagnosis of anaplastic tumors. CONFIRM anti-Cytokeratin (AE1) specifically binds to antigens located in the cytoplasmic regions of normal epithelial cells. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.
anti-Cytokeratin (CAM 5.2) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4555
Ordering Code: 06478425001
Quantity: 50 tests
Controls: Pancreatic Carcinoma and Colon
Isotypes: IgG
Clone Name: Cam 5.2
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE

Anti-Cytokeratin (CAM 5.2) Mouse Monoclonal Primary Antibody (anti-Cytokeratin (CAM 5.2)) is directed against cytokeratin 7 and cytokeratin 8 present on secretory epithelia but not on stratified squamous epithelia. This antibody may be used to aid in the identification of tumors of epithelial origin such as colorectal, pancreatic, and non-small cell lung cancer and in distinguishing carcinomas from other malignant tumors of non-epithelial origin. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

Cytokeratin 5 (SP27) Rabbit Monoclonal Primary Antibody

Catalog Number: 760-4935
Ordering Code: 07292821001
Quantity: 50 tests
Controls: Mesothelioma, Prostate
Isotypes: IgG
Clone Name: Cytokeratin 5 (SP27) Rabbit Monoclonal Primary Antibody
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Cytokeratin 5 (SP27) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of carcinoma and mesothelioma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

anti-Cytokeratin 5/6 (D5/16B4) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4554
Ordering Code: 06478441001
Quantity: 50 tests
Controls: Prostate and Tonsil
Isotypes: IgG1
Clone Name: D5/16B4
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE

Anti-Cytokeratin 5/6 (D5/16B4) Mouse Monoclonal Primary Antibody (anti-Cytokeratin 5/6 (D5/16B4)) detects cytokeratins 5 and 6. Cytokeratin 5 is expressed in various epithelia and mesothelial cells, while cytokeratin 6 is expressed by proliferating squamous epithelium. This antibody exhibits a cytoplasmic staining pattern and may be used to aid in the identification of squamous cell carcinoma and in distinguishing malignant mesothelioma from lung adenocarcinomas. The detection of cytokeratin 5 in myoepithelial cells with this antibody may also be used to aid in the determination of breast and prostate malignancies. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
Cytokeratin 5/14 (EP1601Y/LL002)

Catalog Number: 760-4939
Ordering Code: 07292864001
Quantity: 50 tests
Controls: Esophagus, Squamous Carcinoma
Isotypes: IgG
Clone Name: Cytokeratin 5/14 (EP1601Y/LL002) Rabbit and Mouse Monoclonal Primary Antibody
Species: Rabbit and Mouse Monoclonal
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Cytokeratin 5/14 (EP1601Y/LL002) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of the basaloïd phenotype of breast carcinomas and lung squamous cell carcinomas within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

CONFIRM anti-Cytokeratin 7 (SP52) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4462
Ordering Code: 05986818001
Quantity: 50 tests
Controls: Breast, Salivary Gland, Glandular and Ductal Epithelium of Lung
Clone Name: SP52
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems’ (Ventana) CONFIRM anti-Cytokeratin 7 (SP52) Rabbit Monoclonal Primary Antibody (CONFIRM anti-Cytokeratin 7 (SP52)) is directed against a type II cytokeratin protein expressed by most ductal, glandular and transitional epithelia. Cytokeratin 7 exhibits a cytoplasmic localization. This antibody may be used to aid in the identification of normal and neoplastic cells of ovary, lung and breast epithelial origin which express Cytokeratin 7, and those of colonic and prostate epithelial lineage which lack Cytokeratin 7 production. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

Cytokeratin 8 & 18 (B22.1 & B23.1)

Catalog Number: 760-4344
Ordering Code: 05299776001
Quantity: 50 tests
Controls: Pancreas, Prostate, Salivary Gland
Isotypes: IgG1
Clone Name: B22.1 & B23.1
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Anti-Cytokeratin 8 & 18 (B22.1 & B23.1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cytokeratin 8 & 18 protein in formalin-fixed, paraffin-embedded neoplastic tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
ANTI-CYTOKERATIN 10 (SP99) RABBIT MONOCLONAL PRIMARY ANTIBODY

**Catalog Number:** 790-4562  
**Ordering Code:** 06425135001  
**Quantity:** 50 tests  
**Controls:** Skin  
**Isotypes:** Rabbit Ig  
**Clone Name:** SP99  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

Anti-Cytokeratin 10 (SP99) Rabbit Monoclonal Primary Antibody (anti-Cytokeratin 10 (SP99)) is directed against the 56.5kD member of the type 1 cytokeratin family, cytokeratin 10. Cytokeratin 10 is expressed in keratinizing stratified epithelia, but is absent from the basal layer, in various organs including the skin. Anti-Cytokeratin 10 (SP99) exhibits a cytoplasmic staining pattern and may be used to aid in the identification of well differentiated squamous carcinomas of the cervix and anus. The antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

**CYTOKERATIN 14 (LL002)**

**Catalog Number:** 760-4251  
**Ordering Code:** 05269113001  
**Quantity:** 50 tests  
**Controls:** Squamous Carcinoma, Squamous Mucosa  
**Isotypes:** IgG  
**Clone Name:** LL002  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

Cytokeratin 14 is a 50 kD polypeptide found in basal cell of squamous epithelia, some glandular epithelia, myoepithelium, and mesothelial cells. Anti-CK14 has been demonstrated to be useful in differentiating squamous cell carcinomas from other epithelial tumors. This antibody has also been useful in separating oncocytic tumors of the kidney from renal mimics, as well as in determining metaplastic carcinomas of the breast.

**ANTI-CYTOKERATIN 14 (SP53) RABBIT MONOCLONAL PRIMARY ANTIBODY**

**Catalog Number:** 760-4805  
**Ordering Code:** 06732429001  
**Quantity:** 50 tests  
**Controls:** Prostate, Skin, Squamous Carcinoma  
**Isotypes:** IgG  
**Clone Name:** SP53  
**Species:** Rabbit Monoclonal  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Cytokeratin 14 (SP53) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. This antibody is useful in the identification and diagnosis of squamous cell carcinoma and breast basal like carcinoma within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.
anti-Cytokeratin 17 (SP95) Rabbit Monoclonal Primary Antibody

**Catalog Number:** 790-4560  
**Ordering Code:** 0837368001  
**Quantity:** 50 tests  
**Controls:** Normal Skin, Cervical Carcinoma  
**Isotypes:** Rabbit Ig  
**Clone Name:** SP95  
**Species:** Rabbit  
**Localization:** Membranous, Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
Anti-Cytokeratin 17 (SP95) Rabbit Monoclonal Primary Antibody (anti-Cytokeratin 17 (SP95)) is directed against Cytokeratin 17 expressed in basal cells of complex epithelia, glandular epithelium with myoepithelial component, and transitional and pseudostratified epithelia. This antibody may be used to aid in the identification of squamous cell carcinomas in various tissues including the cervix, lung, and oral cavity. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

Cytokeratin 19 (A53-B/A2.26)

**Catalog Number:** 760-4281  
**Ordering Code:** 0526944001  
**Quantity:** 50 tests  
**Controls:** Colon Carcinoma, Thyroid  
**Isotypes:** IgG 1  
**Clone Name:** A53-B/A2.26  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
Anti-Cytokeratin 19 (A53-B/A2.26) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cytokeratin 19 protein in formalin-fixed, paraffin-embedded neoplastic tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

CONFIRM anti-Cytokeratin 20 (SP33) Rabbit Monoclonal Primary Antibody

**Catalog Number:** 790-4431  
**Ordering Code:** 05587760001  
**Quantity:** 50 tests  
**Controls:** Colon Adenocarcinoma  
**Clone Name:** SP33  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Cytokeratin 20 (SP33) Rabbit Monoclonal Primary Antibody is directed against a type I cytokeratin protein of mature enterocytes and goblet cells of the gastric and intestinal mucosa. This antibody produce a cytoplasmic staining pattern, and may be used to aid in the identification of normal cytokeratin 20 expressing cells and neoplastic cells of colonic epithelial lineage. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.
CONFIRM anti-Desmin (DE-R-11)
Primary Antibody

Catalog Number: 760-2513
Ordering Code: 05267005001
Quantity: 50 tests
Controls: Intestine
Isotypes: IgG, K
Clone Name: DE-R-11
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-Desmin (DE-R-11) Primary Antibody is a mouse monoclonal antibody (IgG1, light chain kappa) directed against desmin. This antibody is intended for use to qualitatively identify desmin in myocytic cells by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-Desmin (DE-R-11) may be used to aid in the identification of cells of normal and abnormal myocytic lineage as an aid in diagnosis of anaplastic tumors. CONFIRM anti-Desmin (DE-R-11) specifically binds to antigens located in the cytoplasm of myocytic cells. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.

Desmoglein 3 (5G11) Mouse Monoclonal Primary Antibody

Catalog Number: 760-5060
Ordering Code: 07709447001
Quantity: 50 tests
Isotypes: IgG
Clone Name: 5G11
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

INTENDED USE
Desmoglein 3 (5G11) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Desmoglein 3 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

DOG1 (SP31) Rabbit Monoclonal Antibody

Catalog Number: 760-4590
Ordering Code: 06433189001
Quantity: 50 tests
Controls: GIST
Isotypes: Rabbit Ig
Clone Name: SP31
Species: Rabbit Monoclonal
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque DOG1 (SP31) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. This antibody is used as an aid in the identification and diagnosis of gastrointestinal stromal tumors (GIST) within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.
VENTANA anti-E-cadherin (36) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4497  
Ordering Code: 05905290001  
Quantity: 50 tests  
Controls: Ductal Breast Carcinoma  
Isotypes: IgG₂ / K  
Clone Name: 36  
Species: Mouse  
Localization: Membranous  
Regulatory Status: IVD

INTENDED USE
VENTANA anti-E-cadherin (36) Mouse Monoclonal Primary Antibody (VENTANA anti-E-cadherin (36)) is directed against the cytoplasmic domain of the human transmembrane protein E-cadherin expressed as a part of the cell-cell adhesion complex in epithelial tissues. Reduction or loss of expression is associated with invasive carcinoma and possibly metastasis in a variety of carcinomas. This antibody may be used to aid in the differentiation of in-situ and/or invasive lobular carcinoma from in situ and/or invasive ductal carcinoma of the breast. This antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. Test results should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

E-Cadherin (EP700Y)

Catalog Number: 760-4440  
Ordering Code: 05973872001  
Quantity: 50 tests  
Controls: Breast, Lung Adenocarcinoma, Pancreas  
Isotypes: IgG  
Clone Name: EP700Y  
Species: Rabbit  
Localization: Membranous  
Regulatory Status: IVD

INTENDED USE
E-Cadherin is an adhesion protein that is expressed in cells of epithelial lineage. Anti-E-Cadherin stains positively in glandular epithelium as well as adenocarcinomas of the lung and G.I. tract, and ovary. It has been useful in distinguishing adenocarcinoma from mesothelioma. Another application involves the differentiation of ductal (which stains positive) vs. lobular cancer of the breast. It has also been shown to be positive in some thyroid carcinomas. Loss of E-Cadherin expression has been suggested as a poor prognostic sign in breast carcinoma and non-small cell lung carcinoma.

CONFIRM anti-Epidermal Growth Factor Receptor (3C6) Primary Antibody

Catalog Number: 790-2988  
Ordering Code: 05278341001  
Quantity: 50 tests  
Controls: Colorectal Adenocarcinoma, Skin  
Isotypes: IgG₁  
Clone Name: 3C6  
Species: Mouse  
Localization: Membranous  
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-Epidermal Growth Factor Receptor (EGFR) (3C6) Primary Antibody is a mouse monoclonal antibody (IgG1) directed against the extracellular domain of human EGFR protein of 170kD. The antibody also recognizes the type III variant of 145kD. This antibody is intended for laboratory use, via light microscopy, for the qualitative detection of EGFR in formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.
**CONFIRM anti-EGFR (5B7) Rabbit Monoclonal Primary Antibody**

- Catalog Number: 790-4347
- Ordering Code: 05278457001
- Quantity: 50 tests
- Controls: Non-Small Cell Lung Carcinoma, Placenta, Skin
- Clone Name: 5B7
- Species: Rabbit
- Localization: Cytoplasmic, Membranous
- Regulatory Status: IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-EGFR (5B7) Rabbit Monoclonal Antibody is a primary antibody designed to qualitatively detect the presence of the internal domain of EGFR via light microscopy in formalin-fixed, paraffin-embedded tissue following staining on a VENTANA automated slide stainer. This antibody is directed against the internal domain of the human Epidermal Growth Factor Receptor (also called EGFR, ErbB1 or HER 1). The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

**anti-EGFR E746-A750 del (SP111) Rabbit Monoclonal Primary Antibody**

- Catalog Number: 790-4650
- Ordering Code: 06521932001
- Quantity: 50 tests
- Controls: EGFR E746-A750 Deletion-Positive Lung Adenocarcinoma Tissue
- Isotypes: IgG
- Clone Name: SP111
- Species: Rabbit Monoclonal
- Localization: Cytoplasmic, Membranous
- Regulatory Status: IVD

**INTENDED USE**

Anti-EGFR E746-A750 del (SP111) Rabbit Monoclonal Primary Antibody (anti-EGFR E746-A750 del (SP111)) exhibits a cell membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of the Epidermal Growth Factor Receptor mutant protein, EGFR E746-A750 del. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

**anti-EGFR L858R (SP125) Rabbit Monoclonal Primary Antibody**

- Catalog Number: 790-4649
- Ordering Code: 06521924001
- Quantity: 50 tests
- Controls: Lung Adenocarcinomas that are positive for the L858R mutation
- Isotypes: IgG
- Clone Name: SP125
- Species: Rabbit Monoclonal
- Localization: Membranous, Cytoplasmic
- Regulatory Status: IVD

**INTENDED USE**

Anti-EGFR L858R (SP125) Rabbit Monoclonal Primary Antibody (anti-EGFR L858R (SP125)) exhibits a cell membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of the Epidermal Growth Factor Receptor mutant protein, EGFR L858R. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
CONFIRM anti-EMA (E29) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4463
Ordering Code: 05878900001
Quantity: 50 tests
Controls: Normal Pancreas
Isotypes: IgG₂a
Clone Name: E29
Species: Mouse
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems’ CONFIRM anti-EMA (E29) Mouse Monoclonal Primary Antibody (CONFIRM anti-EMA (E29)) is directed against epithelial membrane antigen expressed on the apical surface of glandular epithelia. This glycoprotein is primarily membrane localized on normal and tumor tissue, although it may exhibit a cytoplasmic localization in less differentiated carcinomas. This antibody may be used to aid in the identification of epithelial membrane antigen in adenocarcinomas derived from secretory epithelia, malignant mesothelioma, renal cell carcinomas and meningiomas. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

Ep-CAM (Ber-EP4)

Catalog Number: 760-4383
Ordering Code: 05435676001
Quantity: 50 tests
Controls: Adenocarcinoma, Columnar Epithelium
Isotypes: IgG₁/K
Clone Name: Ber-EP4
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Anti-Ep-CAM/Epithelial Specific Antigen (Ber-EP4) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Ep-CAM protein in formalin-fixed, paraffin-embedded neoplastic tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

anti-Epithelial Related Antigen (MOC-31) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4561
Ordering Code: 06374409001
Quantity: 50 tests
Controls: Breast, Colon, Kidney, Lung
Isotypes: IgG₁
Clone Name: MOC-31
Species: Mouse
Localization: Membranous, Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Anti-Epithelial Related Antigen (MOC-31) Mouse Monoclonal Primary Antibody (anti-Epithelial Related Antigen (MOC-31)) is directed against the 40kD epithelial cell adhesion molecule, Epithelial Related Antigen. Epithelial Related Antigen is expressed in most normal epithelial cells in tissues including lung, breast, pancreas, and colon. This antibody exhibits a membranous and/or cytoplasmic staining pattern in neoplastic and normal tissue. Anti-Epithelial Related Antigen (MOC-31) Mouse Monoclonal Primary Antibody may be used as an aid in the differentiation of lung adenocarcinoma and mesothelioma. The antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
INTENDED USE

Anti-ERG (EPR3864) Rabbit Monoclonal Primary Antibody (anti-ERG (EPR3864)) is directed against the C-terminus of the ETS transcription regulator, ERG, and is capable of detecting both wildtype ERG, and truncated ERG resulting from ERG gene rearrangement. This antibody exhibits a nuclear staining pattern and may be used to aid in the identification of prostate adenocarcinomas through the detection of truncated ERG. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody

This antibody is intended for in vitro diagnostic (IVD) use. CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody is intended for laboratory use for the qualitative detection of estrogen receptor (ER) antigen in sections of formalin-fixed, paraffin-embedded breast tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM anti-ER (SP1) is directed against an epitope present on human ER alpha protein located in the nucleus of ER positive normal and neoplastic cells. CONFIRM anti-ER (SP1) is indicated as an aid in the management, prognosis, and prediction of hormone therapy for breast carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. Prescription use only.

anti-EZH2 (SP129) Rabbit Monoclonal Primary Antibody

Anti-EZH2 (SP129) Rabbit Monoclonal Primary Antibody (antiEZH2 (SP129)) is directed against human EZH2 expressed by cancer cells and lymphocytes. This antibody exhibits a nuclear staining pattern and may be used to aid in the identification of prostate cancer, breast cancer and bladder cancer. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
**Factor VIII-R Ag. (polyclonal)**

Catalog Number: 760-2642  
Ordering Code: 05267528001  
Quantity: 50 tests  
Controls: Placenta, Skin  
Clone Name: Polyclonal  
Species: Rabbit  
Localization: Cytoplasmic  
Regulatory Status: IVD  

**INTENDED USE**

Anti-Factor VIII-Related Antigen antibody reacts with endothelial cells and neoplastic blood cells. This antibody has helped to establish the endothelial nature of some lesions of disputed histogenesis, e.g. Kaposi's sarcoma and cardiac myxoma. Not all endothelial cells synthesize (or store) this molecule; therefore, it should not be surprising that not all tumors of endothelial differentiation (benign or malignant) react with this antigen.

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**Factor XIIIa (AC-1A1)**

Catalog Number: 760-4384  
Ordering Code: 05435692001  
Quantity: 50 tests  
Controls: Dermatofibroma  
Isotypes: IgG1  
Clone Name: AC-1A1  
Species: Mouse  
Localization: Cytoplasmic  
Regulatory Status: IVD  

**INTENDED USE**

Factor XIIIa is a blood proenzyme that has been identified in platelets, megakaryocyte, and fibroblast-like mesenchymal or histiocytic cells present in the placenta, uterus, and prostate; it is also present in monocytes and macrophages and dermal dendritic cells. Anti- Factor XIIIa has been found to be useful in differentiating between dermatofibroma (90% (+)), dermatofibrosarcoma protuberans (25%(+)) and desmoplastic malignant melanoma (0%(+)). Factor XIIIa positivity is also seen in capillary hemangioblastoma (100%(+)), hemangiopericytoma (100%(+)), xanthogranuloma (100%(+)), xanthoma (100(+)), hepatocellular carcinoma (93%(+)), glomus tumor (80%(+)), and meningioma (80 % (+)).

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**Factor XIIIa (EP3372)**

Catalog Number: 760-4441  
Ordering Code: 05922470001  
Quantity: 50 tests  
Controls: Dermatofibroma  
Isotypes: IgG  
Clone Name: EP3372  
Species: Rabbit  
Localization: Cytoplasmic  
Regulatory Status: IVD  

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Factor XIIIa (EP3372) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of dermatofibroma within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
INTENDED USE
Anti-Fascin is a very sensitive marker for Reed-Sternberg cells and variants in nodular sclerosis, mixed cellularity, and lymphocyte depletion Hodgkin’s disease. It is uniformly negative in lymphoid cells, plasma cells and myeloid cells. Anti-Fascin is positive in dendritic cells. This marker may be helpful in distinguishing between Hodgkin’s disease and non-Hodgkin’s lymphoma in difficult cases. Also, the lack of expression of Fascin in the neoplastic follicles in follicular lymphoma can be helpful in distinguishing these lymphomas from reactive follicular hyperplasia in which the number of follicular dendritic cells is normal or increased. Anti-Fascin has been suggested as a prognostic marker in neuroendocrine neoplasms of the lung, as well as ovarian cancer.

FITC anti-Albumin Primary Antibody

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) Systems FITC anti-Albumin Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human albumin. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of human albumin in target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-Albumin is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.

FITC anti-C1q Primary Antibody

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) Systems FITC anti-C1q (complement 1q) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human C1q. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of complement 1q in C1q target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-C1q is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.
FITC anti-C3 Primary Antibody

**Catalog Number:** 760-2686  
**Ordering Code:** 05267978001  
**Quantity:** 50 tests  
**Controls:** Frozen, Kidney or Skin from Lupus Cases Containing C3 Deposits  
**Clone Name:** Polyclonal  
**Species:** Goat  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) FITC anti-C3 (complement 3) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human C3. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of complement 3 in C3 target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-C3 is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

FITC anti-C4 Primary Antibody

**Catalog Number:** 760-2687  
**Ordering Code:** 05267960001  
**Quantity:** 50 tests  
**Controls:** Frozen, Diseased Skin or Diseased Renal Tissue  
**Clone Name:** Polyclonal  
**Species:** Sheep  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) Systems FITC anti-C4 (complement 4) Primary Antibody is a sheep derived polyclonal antibody labeled with fluorescein and specifically directed against human C4. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of complement 4 in C4 target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-C4 is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.

FITC anti-Fibrinogen Primary Antibody

**Catalog Number:** 760-2685  
**Ordering Code:** 05267960001  
**Quantity:** 50 tests  
**Controls:** Frozen, Placenta or Tissue Containing Clotted Blood  
**Clone Name:** Polyclonal  
**Species:** Goat  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) FITC anti-Fibrinogen Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human fibrinogen. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of fibrinogen in target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-Fibrinogen is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.
FITC anti-IgA Primary Antibody

Catalog Number: 760-2681
Ordering Code: 05267927001
Quantity: 50 tests
Controls: Frozen, Tonsil or Lymph Node
Clone Name: Polyclonal
Species: Goat
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) Systems FITC anti-IgA (immunoglobulin A) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human IgA. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of immunoglobulin A in IgA target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-IgA is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.

FITC anti-IgG Primary Antibody

Catalog Number: 760-2680
Ordering Code: 05267919001
Quantity: 50 tests
Controls: Frozen, Tonsil or Lymph Node Clotted Blood
Clone Name: Polyclonal
Species: Goat
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) Systems FITC anti-IgG (immunoglobulin G) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human IgG. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of immunoglobulin G in IgG target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-IgG is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.

FITC anti-IgM Primary Antibody

Catalog Number: 760-2682
Ordering Code: 05267935001
Quantity: 50 tests
Controls: Frozen, Tonsil or Lymph Node
Clone Name: Polyclonal
Species: Goat
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) Systems FITC anti-IgM (immunoglobulin M) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human IgM. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of immunoglobulin M in IgM target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-IgM is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.
FITC anti-Kappa Primary Antibody

Catalog Number: 760-2683
Ordering Code: 05267943001
Quantity: 50 tests
Controls: Frozen, Tonsil or Lymph Node Clotted Blood
Clone Name: Polyclonal
Species: Goat
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) Systems FITC anti-Kappa Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human kappa immunoglobulin light chains. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of kappa in target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-Kappa is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.

FITC anti-Lambda Primary Antibody

Catalog Number: 760-2684
Ordering Code: 05267951001
Quantity: 50 tests
Controls: Frozen, Tonsil or Lymph Node
Clone Name: Polyclonal
Species: Burro
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems’ (Ventana) Systems FITC anti-Lambda Primary Antibody is a burro derived polyclonal antibody labeled with fluorescein and specifically directed against human lambda light chains. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of lambda light chains in target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-Lambda is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.

FOXA1 (2F83) Mouse Monoclonal Primary Antibody

Catalog Number: 760-4937
Ordering Code: 07292848001
Quantity: 50 tests
Controls: Breast Carcinoma
Isotypes: IgG
Clone Name: FOXA1 (2F83) Mouse Monoclonal Primary Antibody
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque FOXA1 (2F83) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of breast carcinomas within the context of antibody panels, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.
### FSH (polyclonal)
- **Catalog Number:** 760-2710
- **Ordering Code:** 05268192001
- **Quantity:** 50 tests
- **Controls:** Normal Pituitary
- **Clone Name:** Polyclonal
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
Anti-FSH is a useful marker in classification of pituitary tumors and the study of pituitary disease. It reacts with FSH-producing cells (gonadotrophs).

### Galectin-3 (9C4)
- **Catalog Number:** 760-4256
- **Ordering Code:** 05269164001
- **Quantity:** 50 tests
- **Controls:** Papillary or Follicular Carcinoma of Thyroid
- **Isotypes:** IgG1
- **Clone Name:** 9C4
- **Species:** Mouse
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
Galectin-3 is a 31 kD beta-galactosidase binding lectin. It has been associated with binding to the basement membrane glycoprotein laminin. Anti-Galectin-3 has been demonstrated to be valuable in differentiating between benign and malignant thyroid neoplasms in both histologic sections and fine needle aspiration biopsy material. Anti-Galectin-3 antibody has also been useful in identifying anaplastic large cell lymphoma.

### Gastrin (polyclonal)
- **Catalog Number:** 760-2643
- **Ordering Code:** 05267536001
- **Quantity:** 50 tests
- **Controls:** Stomach
- **Clone Name:** Polyclonal
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
Anti-Gastrin antibody gives positive staining of G-cells of human antral/pyloric mucosa and cells producing gastrin or a structural gastrin analogue as is seen in stomach; no staining of other cells or tissue types has been observed. This antibody may react with sulfated and non-sulfated forms of gastrin. The antibody cross-reacts with more than 50% of the present cholecystokinin octapeptide.

### GATA3 (L50-823) Mouse Monoclonal Primary Antibody
- **Catalog Number:** 760-4897
- **Ordering Code:** 07107749001
- **Quantity:** 50 tests
- **Controls:** Ductal Carcinoma in situ
- **Isotypes:** IgG
- **Clone Name:** L50-823
- **Species:** Mouse
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque GATA3 (L50-823) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of breast carcinomas and urothelial carcinomas within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
** PRIMARY ANTIBODIES **

### GCDFP-15 (EP1582Y) Rabbit Monoclonal Antibody

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<td>Quantity:</td>
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** INTENDED USE **
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque GCDFP-15 (EP1582Y) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of GCDFP-15 within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

### GH (polyclonal)

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</table>

** INTENDED USE **
Anti-GH is a useful marker in classification of pituitary tumors and the study of pituitary disease (acromegaly). It reacts with GH-producing cells. Growth hormone receptors have been found in various non-pituitary cells, including that from hepatocellular carcinoma and various benign and malignant cutaneous lesions.

### Glial Fibrillary Acidic Protein (GFAP) (EP672Y)

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** INTENDED USE **
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Glial Fibrillary Acidic Protein (EP672Y) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of astrocytes and glial lesions in the central nervous system under normal and pathological conditions within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
Glucagon Rabbit Polyclonal Primary Antibody

Catalog Number: 760-2644
Ordering Code: 05267544001
Quantity: 50 tests
Controls: Pancreas
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Glucagon (Polyclonal) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of glucagonomas within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

GLUT1 Rabbit Polyclonal Antibody

Catalog Number: 760-4526
Ordering Code: 06419178001
Quantity: 50 tests
Controls: Malignant Mesothelioma, Colorectal Carcinoma
Isotypes: IgG
Clone Name: Polyclonal
Species: Rabbit
Localization: Membranous
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque GLUT1 (polyclonal) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods.

Glutamine Synthetase (GS-6) Mouse Monoclonal Primary Antibody

Catalog Number: 760-4898
Ordering Code: 07107757001
Quantity: 50 tests
Controls: Hepatocellular Carcinoma
Isotypes: IgG
Clone Name: GS-6
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Glutamine Synthetase (GS-6) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of hepatocellular neoplasms within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
**Glycophorin A (GA-R2)**

**Catalog Number:** 760-4257  
**Ordering Code:** 05269172001  
**Quantity:** 50 tests  
**Controls:** Bone Marrow  
**Isotypes:** IgG2a/K  
**Clone Name:** GA-R2  
**Species:** Mouse  
**Localization:** Membranous  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Glycophorin A (GA-R2) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of benign erythroid proliferation and neoplasms derived from erythroid lineage within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**Glypican-3 (1G12)**

**Catalog Number:** 760-4442  
**Ordering Code:** 05973864001  
**Quantity:** 50 tests  
**Controls:** Hepatocellular Carcinoma  
**Isotypes:** IgG  
**Clone Name:** 1G12  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Glypican-3 (1G12) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of hepatocellular carcinoma (HCC) within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**anti-Glypican 3 (GC33) Mouse Monoclonal Primary Antibody**

**Catalog Number:** 790-4564  
**Ordering Code:** 06483186001  
**Quantity:** 50 tests  
**Controls:** Placenta, Hepatocellular Carcinoma  
**Isotypes:** IgG2a  
**Clone Name:** GC33  
**Species:** Mouse  
**Localization:** Granular Cytoplasmic/Membrane  
**Regulatory Status:** IVD

**INTENDED USE**

Anti-Glypican 3 (GC33) Mouse Monoclonal Primary Antibody (antiGlypican 3 (GC33)) is directed against the heparan sulfate proteoglycan, glypican 3. This antibody may be used to aid in the differentiation of hepatocellular carcinoma from normal liver or benign lesions. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
PRIMARY ANTIBODIES

**Granzyme B (polyclonal)**

- **Catalog Number:** 760-4283
- **Ordering Code:** 05269466001
- **Quantity:** 50 tests
- **Controls:** Tonsil
- **Clone Name:** Polyclonal
- **Species:** Rabbit
- **Localization:** Granular, Cytotoxic T lymphocytes, Natural Killer Cells
- **Regulatory Status:** IVD

**INTENDED USE**

Granzymes are serine proteases which are stored in specialized lytic granules of cytotoxic T lymphocytes and in natural killer cells. Anti-Granzyme B has been useful in diagnosing Natural killer/T cell lymphoma, as well as anaplastic large cell lymphoma. High percentages of cytotoxic T cells have been shown to be an unfavorable prognostic indicator in Hodgkin's disease.

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**HBME-1 (HBME-1)**

- **Catalog Number:** 760-4445
- **Ordering Code:** 05973813001
- **Quantity:** 50 tests
- **Controls:** Mesothelioma, Thyroid Carcinoma
- **Isotypes:** IgM/K
- **Clone Name:** HBME-1
- **Species:** Mouse
- **Localization:** Cytoplasmic, Membranous
- **Regulatory Status:** IVD

**INTENDED USE**

Anti-HBME-1 has been demonstrated to label mesothelial cells, both benign and malignant (malignant mesothelioma) and thus has been used in distinguishing mesothelioma from adenocarcinomas of various origins. More recently this antibody has been used to distinguish Thyroid carcinomas (both Follicular and Papillary) from benign thyroid lesions.

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**hCG (polyclonal)**

- **Catalog Number:** 760-2650
- **Ordering Code:** 05267617001
- **Quantity:** 50 tests
- **Controls:** Placenta
- **Clone Name:** Polyclonal
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

hCG is a protein secreted in large quantities by normal trophoblasts; the antibody detects cells and tumors of trophoblastic origin such as Choriocarcinoma. Large Cell Carcinoma and Adenocarcinoma of Lung demonstrate hCG positivity in 90% and 60% of cases respectively. 20% of Squamous Cell Lung Carcinomas are positive for hCG. hCG expression by non-trophoblastic tumors may indicate aggressive behavior since it has been observed that hCG may play a role in the host response to a given tumor.
VENTANA anti-\textit{Helicobacter pylori} (SP48) Rabbit Monoclonal Primary Antibody


catalog number: 790-1014 790-1015
ordering code: 06425607001 6425623001
quantity: 50 tests 250 tests
controls: \textit{H. pylori}-infected stomach
clone name: \textit{SP48}
species: rabbit
localization: whole \textit{H. pylori} organism
regulatory status: 510(k)

intended use
VENTANA anti-\textit{Helicobacter pylori} (SP48) Rabbit Monoclonal Primary Antibody (VENTANA anti-\textit{H. pylori} (SP48)) is designed to qualitatively detect the presence of \textit{H. pylori} in formalin-fixed, paraffin-embedded gastric biopsy tissue via light microscopy. Immunohistochemical staining with this antibody product may aid in the diagnosis of \textit{H. pylori} infection. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

Hemoglobin A (SP212) Rabbit Monoclonal Primary Antibody

catalog number: 760-4936
ordering code: 07292830001
quantity: 50 tests
controls: bone marrow
isotypes: IgG
clone name: Hemoglobin A (SP212) Rabbit Monoclonal Primary Antibody
species: rabbit
localization: cytoplasmic
regulatory status: IVD

intended use
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Hemoglobin A (SP212) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of erythrocytes and precursors within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

Hepatocyte Specific Antigen (OCH1E5)

catalog number: 760-4350
ordering code: 05269792001
quantity: 50 tests
controls: liver
isotypes: IgG1/K
clone name: OCH1E5
species: mouse
localization: cytoplasmic
regulatory status: IVD

intended use
Anti-Hepatocyte Specific Antigen recognizes both benign and malignant liver derived tissues including such tumors as hepatoblastoma, hepatocellular carcinoma, and hepatic adenoma. It recognizes both normal adult and fetal liver tissue. The typical pattern is a granular cytoplasmic staining. This antibody is useful in differentiating hepatocellular carcinomas with adenoid features from adenocarcinomas, either primary in the liver or metastatic lesions to the liver. In recognizing hepatoblastoma, it is useful in differentiating this entity from other small round cell tumors.
INTENDED USE

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems, Inc.'s (Ventana) PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody (PATHWAY HER2 (4B5)) is a rabbit monoclonal antibody intended for laboratory use for the semi-quantitative detection of HER2 antigen in sections of formalin-fixed, paraffin-embedded normal and neoplastic tissue on a VENTANA automated immunohistochemistry slide staining device. It is indicated as an aid in the assessment of breast cancer patients for whom Herceptin treatment is considered.

Note: All of the patients in the Herceptin clinical trials were selected using a clinical trial assay. None of the patients in those trials were selected using PATHWAY anti-HER-2/neu (4B5). PATHWAY anti-HER-2/neu (4B5) was compared to PATHWAY HER-2 (clone CB11) Primary Antibody on an independent sample set and found to provide acceptably concordant results. The actual correlation of PATHWAY anti-HER-2/neu (4B5) to clinical outcome has not been established.

The VIAS Image Analysis System is an adjunctive optional computer-assisted image analysis system functionally connected to an interactive microscope. It is intended for use as an aid to the pathologist in the detection, classification and counting of cells of interest based on marker intensity, size and shape using appropriate controls to assure the validity of the VIAS scores. Prescription use only.

HGAL (MRQ-49) Mouse Monoclonal Antibody

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque HGAL (MRQ-49) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the identification of follicular lymphoma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

HHV-8 (13B10)

INTENDED USE

Human herpesvirus type 8 (HHV-8) is the likely etiological agent of Kaposi's sarcoma (KS). HHV-8 DNA sequences have been found in Kaposi's sarcoma lesions, primary effusion lymphoma, and multicentric Castleman's disease via polymerase chain reaction and in situ hybridization. Latent nuclear antigen (LNA-1, LNA, LANA-1), also known as ORF73, is a 222- or 234 kD protein that is consistently expressed in HHV-8 infected cells. Anti-HHV-8 labels the latent nuclear antigen protein via immunohistochemistry.
**Human Equilibrative Nucleoside Transporter 1 (SP120) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 790-4852  
**Ordering Code:** 06903444001  
**Quantity:** 50 tests  
**Controls:** Adrenal Cortex, Kidney, Thyroid, Tonsil, Normal Pancreas  
**Isotypes:** IgG  
**Clone Name:** SP120  
**Species:** Rabbit Monoclonal  
**Localization:** Membranous, Cytoplasmic  
**Regulatory Status:** IVD  

**INTENDED USE**  
Anti-hENT1 (SP120) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of hENT1 in formalin-fixed, paraffin-embedded tissue. This antibody exhibits a membranous and/or cytoplasmic staining pattern and may be used to detect hENT1 protein in benign and neoplastic human pancreatic, breast, lymphoid or lung tissue stained with a VENTANA immunohistochemical automated slide stainer. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

**Human Placental Lactogen (hPL)(polyclonal)**

**Catalog Number:** 760-4443  
**Ordering Code:** 05973830001  
**Quantity:** 50 tests  
**Controls:** Placenta  
**Isotypes:** IgG  
**Clone Name:** Polyclonal  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD  

**INTENDED USE**  
Human placental lactogen (hPL), also previously known as ‘human chorionic somatomammotropin’, is a 22 kD protein with partial homology to growth hormone. hPL is first detectable in the maternal serum in the fifth week of gestation and reaches a plateau by the thirty-fourth week. hPL has been demonstrated by immunochemistry in the syncytiotrophoblastic cells of choriocarcinoma. A rare variant of trophoblastic tumor has been reported in the testis with resemblance to uterine placental site trophoblastic tumor. It consisted purely of intermediate trophoblasts, which was diffusely positive for hPL and focally for B-hCG.

**IgA (polyclonal)**

**Catalog Number:** 760-2652  
**Ordering Code:** 05267625001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Tonsil  
**Clone Name:** Polyclonal  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD  

**INTENDED USE**  
Anti-IgA antibody reacts with surface immunoglobulin IgA alpha chains. It is useful when identifying leukemias, plasmacytomas, and B-cell lineage derived Hodgkin's lymphomas. Due to the restricted expression of heavy and light chains in these diseases, demonstration of B-cell lymphoma/plasmacytoma is aided with this antibody.
**INTENDED USE**

Anti-IgD antibody reacts with surface immunoglobulin IgD delta chains. This antibody is useful when identifying leukemias, plasmacytomas, and B-cell lineage derived lymphomas (in particular Marginal Zone Lymphoma). Cytoplasmic staining is easily identified on paraffin tissue. Surface immunoglobulin is difficult to demonstrate on paraffin sections but can be demonstrated on frozen sections.

**CONFIRM anti-IGF-1R (G11) Rabbit Monoclonal Primary Antibody**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-IGF-1R (G11) Primary Antibody is a rabbit monoclonal antibody directed against IGF-1R. This antibody is intended for use to qualitatively identify IGF-1R positive cells by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a Ventana automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

**INTENDED USE**

Anti-IgG Polyclonal Primary Antibody is intended for laboratory use in the detection of the IgG protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
**IgG4 (MRQ-44) Mouse Monoclonal Antibody**

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque IgG4 (MRQ-44) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of IgG4-related sclerosing diseases within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

**IgM (polyclonal)**

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**INTENDED USE**

Anti-IgM antibody reacts with surface immunoglobulin IgM mu chains. IgM is one of the predominant surface immunoglobulins on B-lymphocytes. This antibody is useful when identifying lymphomas, plasmacytomas, and B-cell lineage derived Hodgkin's lymphomas. Due to the restricted expression of heavy and light chains in these diseases, demonstration of B-cell lymphomas is possible with clonal gene rearrangement studies.

**Inhibin, alpha (R1)**

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**INTENDED USE**

Anti-Inhibin, alpha Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Inhibin, alpha protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
**anti-INI-1 (MRQ-27) Mouse Monoclonal Primary Antibody**

- **Catalog Number:** 760-4615
- **Ordering Code:** 06523862001
- **Quantity:** 50 tests
- **Controls:** Brain, Endothelial Cells, Astrocytoma
- **Clone Name:** MRQ-27
- **Species:** Mouse
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque INI-1 (MRQ-27) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. This antibody is used subsequent to the diagnosis of malignancy as an aid to classify the disease as malignant rhabdoid tumors within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

**Insulin (polyclonal)**

- **Catalog Number:** 760-2655
- **Ordering Code:** 05267650001
- **Quantity:** 50 tests
- **Controls:** Pancreas
- **Clone Name:** Polyclonal
- **Species:** Guinea Pig
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
Anti-Insulin is produced in the beta cells of the pancreas. The presence of insulin in the cytoplasm of islet tumors is the most reliable indication of functional insulinomas. Defective insulin storage occurs in insulinomas therefore, many sections of the tumor should be stained with both insulin and C peptide.

**CONFIRM anti-Kappa Rabbit Polyclonal Primary Antibody**

- **Catalog Number:** 760-2514
- **Ordering Code:** 05267013001
- **Quantity:** 50 tests
- **Controls:** Lymph Node, Tonsil
- **Clone Name:** Polyclonal
- **Species:** Rabbit
- **Localization:** Surface Membrane, Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Kappa Rabbit Polyclonal Primary Antibody is directed against kappa immunoglobulin light chains. Staining for kappa light chains can be used to aid in the identification of cells of normal and abnormal B cell lineage. This antibody is intended for laboratory use to qualitatively stain B cells and plasma cells expressing kappa light chain immunoglobulins in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-Kappa Rabbit Polyclonal specifically binds to antigens located in the cell membrane and cytoplasmic regions of normal B cells and plasma cells. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription use only.
CONFIRM anti-Keratin (34βE12) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4373
Ordering Code: 0547926001
Quantity: 50 tests
Controls: Prostate
IgG Isotypes: 34βE12
Clone Name: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic use. Ventana Medical Systems’ CONFIRM® anti-Keratin (34βE12) Mouse Monoclonal Primary Antibody recognizes cytokeratins 1, 5, 10, and 14 and is used as an aid in the identification of basal cells in prostate, and myoepithelial cells in breast, via light microscopy in formalin-fixed, paraffin-embedded tissue following staining on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

CONFIRM anti-Keratin (AE3) Primary Antibody

Catalog Number: 790-2909
Ordering Code: 05278040001
Quantity: 50 tests
Controls: Bladder, Prostate, Salivary Gland
IgG Isotypes: AE3
Clone Name: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic use. Ventana Medical Systems’ (Ventana) CONFIRM anti-Keratin (AE3) is a mouse monoclonal antibody (IgG1, kappa) directed against basic cytokeratins of h 65-67, 64, 59, 56, and 52 kD. Unexpected antigen expression or loss of expression may occur, especially in neoplasms. Occasionally stromal elements surrounding heavily stained tissue or cells will show immunoreactivity. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CONFIRM anti–Ki–67 (30-9) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4286
Ordering Code: 05278384001
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Clone Name: 30-9
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' CONFIRM anti–Ki–67 (30-9) Primary Antibody is a rabbit monoclonal antibody (IgG) directed against C-terminal portion of Ki–67 antigen. Staining for Ki–67 can be used to aid in assessing the proliferative activity of normal and neoplastic tissue.1,2,3 This antibody is intended for use to identify stained proliferating cells by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.


Ksp-cadherin (MRQ-33)

Catalog Number: 760-4387
Ordering Code: 05463548001
Quantity: 50 tests
Controls: Chromophobe Renal Cell Carcinoma, Kidney
Isotypes: IgG
Clone Name: MRQ-33
Species: Mouse
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

INTENDED USE

Kidney-specific cadherin (Ksp-Cadherin) is a novel, kidney-specific member of the cadherin family of cell adhesion molecules. Within the kidney, Ksp-Cadherin is found exclusively in the basolateral membrane of renal tubular epithelial cells and collecting duct cells, and not in glomeruli, renal interstitial cells, or blood vessels. Different cadherins, including E-cadherin, cadherin-6, and N-cadherin, have been investigated in renal cell cancers, demonstrating possible correlations of tumor dedifferentiation and the presence of lymph node metastasis with loss of cadherins. Mazal et al. investigated the utility of using Ksp-Cadherin to distinguish chromophobe renal cell carcinoma from oncocytoma. He found a membranous pattern of staining in 96% of 30 chromophobe carcinomas, and in only 6% of 31 oncocytomas leading them to conclude that this is a useful antibody in differentiating these two lesions. Shen et al., on the other hand, found Ksp-Cadherin positivity in 100% of 13 chromophobe RCCs, and 95% of 20 oncocytomas.
CONFIRM anti-Lambda Rabbit Polyclonal Primary Antibody

**Catalog Number:** 760-2515  
**Ordering Code:** 05267021001  
**Quantity:** 50 tests  
**Controls:** Tonsil  
**Clone Name:** Polyclonal  
**Species:** Rabbit  
**Localization:** Surface Membrane, Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-Lambda Rabbit Polyclonal Primary Antibody is directed against lambda immunoglobulin light chains. Staining for lambda light chains can be used to aid in the identification of cells of normal and abnormal B cell lineage. This antibody is intended for laboratory use to qualitatively stain B cells and plasma cells expressing lambda light chain immunoglobulins in sections of formalin-fixed, paraffin-embedded tissue in a VENTANA automated slide stainer. CONFIRM anti-Lambda Rabbit Polyclonal specifically binds to antigens located in the cell membrane and cytoplasmic regions of normal B cells and plasma cells. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription use only.

LH (polyclonal)

**Catalog Number:** 760-2802  
**Ordering Code:** 05268222001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Tonsil  
**Clone Name:** Polyclonal  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
Anti-LH is a useful marker in classification of pituitary tumors and the study of pituitary disease. It reacts with LH-producing cells (gonadotrophs).

CONFIRM anti-LMO2 (1A9-1) Mouse Monoclonal Primary Antibody

**Catalog Number:** 790-4368  
**Ordering Code:** 05479274001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Tonsil  
**Isotypes:** IgG, K  
**Clone Name:** 1A9-1  
**Species:** Mouse  
**Localization:** Nuclear  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-LMO2 (1A9-1) Mouse Monoclonal Primary Antibody is designed to qualitatively detect the presence of LMO2 expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue. Positive staining results may aid in the classification of B-cell lymphomas. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.
**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque LMO2 (SP51) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. LIM-only transcription factor-2 (LMO2) antibody is useful in the diagnosis of follicular lymphoma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

**LM02 (SP51)**

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**Lysozyme (polyclonal)**

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**INTENDED USE**

Anti-Lysozyme stains myeloid cells, histiocytes, granulocytes, macrophages, and monocytes in human tonsil, colon and skin. It is an important marker that may demonstrate the myeloid or monocytic nature of acute leukemia. The restrictive nature of anti-lysozyme antibody staining suggests that lysozyme may be synthesized predominantly in reactive histiocytes rather than in resting, unstimulated phagocytes. Anti-lysozyme may aid in the identification of histiocytic neoplasias, large lymphocytes and classifying lymphoproliferative disorders.

**Macrophage (HAM-56)**

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**INTENDED USE**

Anti-HAM-56 reacts with tingible macrophages, interdigitating macrophages of lymph nodes and tissue macrophages, e.g. Kupffer cells of the liver and alveolar macrophages of the lung. The antibody also stains a subpopulation of endothelial cells, most prominently those of the capillaries and smaller blood vessels. Anti-HAM-56 antibody reacts with monocytes, but is unreactive with B and T-lymphocytes.
Mammaglobin (31A5)

Catalog Number: 760-4263  
Ordering Code: 5260253001  
Quantity: 50 tests  
Controls: Breast Carcinoma  
Clone Name: 31A5  
Species: Rabbit  
Localization: Cytoplasmic  
Regulatory Status: IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Mammaglobin (31A5) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in identification of substantial proportion of primary and metastatic breast carcinomas within the context of an antibody panel, the patient's clinical history and other diagnostic tests evaluated by a qualified pathologist.

CONFIRM anti-MART-1/melan A (A103)  
Mouse Monoclonal Primary Antibody

Catalog Number: 790-2990  
Ordering Code: 05278350001  
Quantity: 50 tests  
Controls: Melanoma, Normal Skin  
Isotypes: IgG1  
Clone Name: A103  
Species: Mouse  
Localization: Cytoplasmic  
Regulatory Status: IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems, Inc.’s (Ventana) CONFIRM anti-MART-1/melan A (A103) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody (IgG1) directed against melan A. This antibody is designed to qualitatively detect the presence of melan A by light microscopy in sections of formalin-fixed, paraffin-embedded tissue. Positive staining may aid in the classification of melanoma. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

Melanoma Associated Antigen (KBA.62)  
Mouse Monoclonal Antibody

Catalog Number: 760-4527  
Ordering Code: 06419186001  
Quantity: 50 tests  
Controls: Melanoma  
Isotypes: IgG1  
Clone Name: KBA.62  
Species: Mouse  
Localization: Cytoplasmic  
Regulatory Status: IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque anti-Melanoma Associated Antigen (KBA.62) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using VENTANA BenchMark® automated IHC test methods. Use of this antibody is indicated as an aid in the diagnosis of primary and metastatic melanoma within the context of an antibody panel, the patient's clinical history and other diagnostic tests evaluated by a qualified pathologist or physician.
**Melanoma Associated Antigen (PNL2)**

**Mouse Monoclonal Antibody**

- **Catalog Number:** 760-4528
- **Ordering Code:** 06419194001
- **Quantity:** 50 tests
- **Controls:** Melanoma
- **Isotypes:** IgG1
- **Clone Name:** PNL2
- **Species:** Mouse
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque anti-Melanoma Associated Antigen (PNL2) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using VENTANA BenchMark® automated IHC test methods. Use of this antibody is indicated as an aid in diagnostic determination of the diagnosis of primary and metastatic melanoma within the context of an antibody panel, the patient's clinical history and other diagnostic tests evaluated by a qualified pathologist or physician.

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**Melanoma Triple Cocktail (HMB45+A103+T311)**

**Primary Antibody**

- **Catalog Number:** 790-4677
- **Ordering Code:** 06527787001
- **Quantity:** 50 tests
- **Controls:** Melanoma
- **Clone Name:** HMB45+A103+T311
- **Species:** N/A
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

Melanoma Triple Cocktail (HMB45+A103+T311) is an antibody cocktail of anti-Melanosome (HMB45), anti-MART-1/melan A (A103), and anti-Tyrosinase (T311) mouse monoclonal antibodies. This antibody cocktail demonstrates cytoplasmic staining and may be used to aid in the identification of melanoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

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**CONFIRM anti-Melanosome (HMB45)**

**Mouse Monoclonal Primary Antibody**

- **Catalog Number:** 790-4366
- **Ordering Code:** 05479282001
- **Quantity:** 50 tests
- **Controls:** Melanoma, Skin
- **Isotypes:** IgG1/K
- **Clone Name:** HMB45
- **Species:** Mouse
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems’ (Ventana) CONFIRM anti-Melanosome (HMB45) is a mouse monoclonal antibody (IgG1, kappa) directed against an oncofetal antigen present within immature melanosomes in the cytoplasm of activated and neoplastic melanocytes. CONFIRM anti-Melanosome (HMB45) is intended for laboratory use to qualitatively detect, via light microscopy, cells containing immature melanosomes in sections of formalin-fixed, paraffin-embedded tissue following staining on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.
**CONFIRM anti-MITF (C5/D5) Mouse Monoclonal Primary Antibody**

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-MITF (C5/D5) Mouse Monoclonal Primary Antibody is a mouse monoclonal cocktail. This antibody cocktail reagent detects microphthalmia transcription factor (MITF) proteins 52-56KD of MITF expressing cells in normal and neoplastic tissues. This antibody is used in the identification of melanotic lesions such as malignant melanoma and melanotic neurofibroma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining or absence of staining must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

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**anti-MLH-1 (M1) Mouse Monoclonal Primary Antibody**

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**INTENDED USE**

Anti-MLH-1 (M1) Mouse Monoclonal Primary Antibody (anti-MLH-1 (M1)) is used to qualitatively identify human DNA mismatch repair (MMR) protein MLH1, expressed in the nucleus of normal proliferating cells. Deficient or low levels of MLH1 are associated with colorectal and other cancers. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

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**MSH2 (G219-1129) Mouse Monoclonal Antibody**

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque MSH2 (G219-1129) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of microsatellite instability within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
CONFIRM anti-MSH6 (44) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4455
Ordering Code: 05929911001
Quantity: 50 tests
Controls: Breast Carcinoma, Colon Carcinoma
Isotypes: IgG1
Clone Name: 44
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

**INTENDED USE**
Ventana Medical Systems’ (Ventana) CONFIRM anti-MSH6 (44) Mouse Monoclonal Antibody is used to qualitatively identify human DNA mismatch repair (MMR) protein MSH6, expressed in the nucleus of normal proliferating cells. Deficient or low levels of MSH6 are associated with colorectal and other cancers. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

MUC1 (H23) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4574
Ordering Code: 06316514001
Quantity: 50 tests
Controls: Breast, Lung, Pancreas
Isotypes: IgG
Clone Name: H23
Species: Mouse Monoclonal
Localization: Membranous, Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**
Anti-MUC1 (H23) Mouse Monoclonal Primary Antibody is directed against the membrane bound, glycosylated phosphoprotein MUC1. This antibody may be used to aid in the identification of normal and neoplastic MUC1 expressing cells. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded human tissue. MUC1 is overexpressed in breast carcinoma and non-small cell lung carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

MUC2 (MRQ-18)

Catalog Number: 760-4388
Ordering Code: 05463556001
Quantity: 50 tests
Controls: Colon, Colon Adenocarcinoma
Isotypes: IgG1/K
Clone Name: MRQ-18
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**
Mucins are high molecular weight glycoproteins which constitute the major component of the mucus layer that protects the gastric epithelium from chemical and mechanical aggressions. In humans, at least 14 mucin genes have been identified that code for the mucin proteins. They are designated as MUC1, MUC2, MUC3, MUC4, MUC5AC, MUC5B, MUC6, MUC7, MUC8, MUC9, MUC11, MUC12, MUC13 and MUC16. Mucins share a common feature of a tandem-repeat domain rich in serine and threonine residues. These amino acid residues are potential O-glycosylation sites for attachment of the O-glycan chains that constitute up to 80% of the molecular weight of the final mucin glycoprotein. The heterogeneous pattern of mucin expression, including the expression of the intestinal mucin MUC2, may provide new insights into the differentiation pathways of gastric carcinoma. The pattern of mucin expression may also be used as a clue to bring new insights into the biological behavior of distinct clinicopathological entities related to the localization of gastric carcinoma, namely proximal and distal gastric carcinomas. Pinto-de-Sousa et al. have shown in a comprehensive study of gastric carcinomas evaluated for expression of several mucins (MUC1, MUC2, MUC5AC and MUC6) that: (1) mucin expression is associated with tumor type (MUC5AC with diffuse and infiltrative carcinomas and MUC2 with mucinous carcinomas) but not with the clinicobiological behavior of the tumors; and (2) mucin expression is associated with tumor location (MUC5AC with antrum carcinomas and MUC2 with cardia carcinomas), indirectly reflecting differences in tumor differentiation according to tumor location.
MUC5AC (MRQ-19)

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**INTENDED USE**

Mucins are high molecular weight glycoproteins which constitute the major component of the mucus layer that protects the gastric epithelium from chemical and mechanical aggressions. In humans, at least 14 mucin genes have been identified that code for the mucin proteins. They are designated as MUC1, MUC2, MUC3, MUC4, MUC5AC, MUC5B, MUC6, MUC7, MUC8, MUC9, MUC11, MUC12, MUC13 and MUC16. Mucin genes are expressed in a regulated cell- and tissue-specific manner. The stomach provides a good example of such differential expression of mucin genes. MUC1 is detected in mucus cells of the surface epithelium and neck region of the gastric antrum, as well as in pyloric glands and oxyntic glands of the body region. MUC5AC is highly expressed in foveolar epithelium of both body and antrum, whereas MUC6 protein expression is limited to mucus neck cells of the body and pyloric glands of the antrum. The mucin expression pattern of gastric carcinoma is heterogeneous. It includes mucins normally expressed in gastric mucosa (MUC1, MUC5AC and MUC6) and de novo expression of the intestinal mucin MUC2. The heterogeneous pattern of mucin expression, including the expression of the intestinal mucin MUC2, may provide new insights into the differentiation pathways of gastric carcinoma. Pinto-de-Sousa et al. have shown in a comprehensive study of gastric carcinomas evaluated for expression of several mucins (MUC1, MUC2, MUC5AC and MUC6) that: (1) mucin expression is associated with tumor type (MUC5AC with diffuse and infiltrative carcinomas and MUC2 with mucinous carcinomas) but not with the clinico-biological behavior of the tumors; and (2) mucin expression is associated with tumor location (MUC5AC with antrum carcinomas and MUC2 with cardia carcinomas), indirectly reflecting differences in tumor differentiation according to tumor location.

MUC6 (MRQ-20)

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<td>IVD</td>
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**INTENDED USE**

Mucins are high molecular weight glycoproteins which constitute the major component of the mucus layer that protects the gastric epithelium from chemical and mechanical aggressions. In humans, at least 14 mucin genes have been identified that code for the mucin proteins. They are designated as MUC1, MUC2, MUC3, MUC4, MUC5AC, MUC5B, MUC6, MUC7, MUC8, MUC9, MUC11, MUC12, MUC13 and MUC16. Mucin genes are expressed in a regulated cell- and tissue-specific manner. The stomach provides a good example of such differential expression of mucin genes. MUC1 is detected in mucus cells of the surface epithelium and neck region of the gastric antrum, as well as in pyloric glands and oxyntic glands of the body region. MUC5AC is highly expressed in foveolar epithelium of both body and antrum, whereas MUC6 protein expression is limited to mucus neck cells of the body and pyloric glands of the antrum. The mucin expression pattern of gastric carcinoma is heterogeneous. It includes mucins normally expressed in gastric mucosa (MUC1, MUC5AC and MUC6) and de novo expression of the intestinal mucin MUC2. The heterogeneous pattern of mucin expression, including the expression of the intestinal mucin MUC2, may provide new insights into the differentiation pathways of gastric carcinoma. Pinto-de-Sousa et al. have shown in a comprehensive study of gastric carcinomas evaluated for expression of several mucins (MUC1, MUC2, MUC5AC and MUC6) that: (1) mucin expression is associated with tumor type (MUC5AC with diffuse and infiltrative carcinomas and MUC2 with mucinous carcinomas) but not with the clinico-biological behavior of the tumors; and (2) mucin expression is associated with tumor location (MUC5AC with antrum carcinomas and MUC2 with cardia carcinomas), indirectly reflecting differences in tumor differentiation according to tumor location.
PRIMARY ANTIBODIES

MUM1 (MRQ-43)

Catalog Number: 760-4529
Ordering Code: 064190208001
Quantity: 50 tests
Controls: Tonsil
Isotypes: IgG
Clone Name: MRQ-43
Species: Rabbit
Localization: Nuclear, Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque MUM1 (MRQ-43) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue using IHC test methods. Use of this antibody is indicated as an aid in the identification of plasma cells, B-cells in the light zone of the germinal center and activated T-cells, and in the diagnosis of classic Hodgkin disease, subtype of B-cell lymphomas, and plasma cell tumors within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

Myeloperoxidase (polyclonal)

Catalog Number: 760-2659
Ordering Code: 05267920001
Quantity: 50 tests
Controls: Bone Marrow
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Anti-Myeloperoxidase Polyclonal Primary Antibody is intended for laboratory use in the detection of the myeloperoxidase protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

MyoD1 (EP212) Rabbit Monoclonal Primary Antibody

Catalog Number: 760-4900
Ordering Code: 07107730001
Quantity: 50 tests
Controls: Rhabdomyosarcoma
Isotypes: IgG
Clone Name: EP212
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque MyoD1 (EP212) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of rhabdomyosarcoma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
**Myogenin (F5D)**

**Catalog Number:** 760-2832  
**Ordering Code:** 05268290001  
**Quantity:** 50 tests  
**Controls:** Rhabdomyosarcoma  
**Isotypes:** IgG1/K  
**Clone Name:** F5D  
**Species:** Mouse  
**Localization:** Nuclear  
**Regulatory Status:** IVD

**INTENDED USE**
Anti-Myogenin labels the nuclei of myoblasts in developing muscle tissue, and is expressed in tumor cell nuclei of rhabdomyosarcoma and some leiomyosarcomas. Positive nuclear staining may occur in Wilm’s tumor.

---

**Myoglobin (polyclonal)**

**Catalog Number:** 760-2660  
**Ordering Code:** 05267706001  
**Quantity:** 50 tests  
**Controls:** Skeletal Muscle  
**Clone Name:** Polyclonal  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
Immunostaining with anti-myoglobin provides a specific, sensitive and practical procedure for the identification of tumors of muscle origin. Since myoglobin is found exclusively in skeletal and cardiac muscle and is not present in any other cells of the human body, it may be used to distinguish rhabdomyosarcoma from other soft tissue tumors. Anti-myoglobin staining is also useful when demonstrating rhabdomyoblastic differentiation in other tumors, e.g. neurogenic sarcomas, and malignant mixed mesodermal tumors of the uterus and ovary.

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**Myosin, Smooth Muscle (SMMS-1)**

**Catalog Number:** 760-2704  
**Ordering Code:** 05268133001  
**Quantity:** 50 tests  
**Controls:** Breast, Intestine  
**Isotypes:** IgG1/K  
**Clone Name:** SMMS-1  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Myosin, Smooth Muscle (SMMS-1) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of smooth muscle and myoepithelial tumors within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
Napsin A (MRQ-60) Mouse Monoclonal Primary Antibody

- Catalog Number: 760-4867
- Ordering Code: 07047720001
- Quantity: 50 tests
- Controls: Lung Adenocarcinoma, Renal Cell Carcinoma
- Isotypes: IgG1 / K
- Clone Name: MRQ-60
- Species: Mouse Monoclonal
- Localization: Cytoplasmic
- Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Napsin A (MRQ-60) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of napsin A protein over-expression in various lung adenocarcinomas within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

Napsin A (polyclonal)

- Catalog Number: 760-4446
- Ordering Code: 05973805001
- Quantity: 50 tests
- Controls: Lung Adenocarcinoma
- Isotypes: IgG
- Clone Name: Polyclonal
- Species: Rabbit
- Localization: Cytoplasmic
- Regulatory Status: IVD

INTENDED USE
Napsin is a pepsin-like aspartic proteinase, in the A1 clan of the AA clade of proteinases. There are two closely related napsins, napsin A and napsin B. Napsin A is expressed as a single chain protein with the molecular weight of approximately 38 kDa. Immunohistochemical studies revealed high expression levels of napsin A in human lung and kidney but low expression in spleen. Napsin A is expressed in type II pneumocytes and in adenocarcinomas of lung. The high specificity expression of napsin A in adenocarcinomas of lung is useful to distinguish primary lung adenocarcinomas from adenocarcinomas of other organs.

Negative Control (Monoclonal)

- Catalog Number: 760-2014
- Ordering Code: 05266670001
- Quantity: 250 tests
- Controls: Kidney
- Clone Name: MOPC21
- Species: Mouse
- Localization: Cytoplasmic
- Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Negative Control (Monoclonal) is a mouse monoclonal antibody (MOPC-211) which is not directed against a known epitope present in human tissue. The reagent is intended for use as a negative control in qualitative staining of sections of routine formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.
CONFIRM Negative Control Rabbit Ig

- **Catalog Number:** 760-1029
- **Ordering Code:** 05266238001
- **Quantity:** 250 tests
- **Controls:** See Package Insert
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM Negative Control Rabbit Ig is intended for laboratory use as a control for nonspecific binding of rabbit immunoglobulin in sections of formalin-fixed, paraffin-embedded tissue on VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

Nerve Growth Factor Receptor (NGFR) (MRQ-21)

- **Catalog Number:** 760-4391
- **Ordering Code:** 05463599001
- **Quantity:** 50 tests
- **Controls:** Ganglia, Neurons, Malignant Melanoma Cells, Myoepithelial Cells of Breast Ducts
- **Isotypes:** IgG1
- **Clone Name:** MRQ-21
- **Species:** Mouse
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

NGFR, a 75 kd glycoprotein (also known as P-75NTR), is the first of neurotrophin receptors to be isolated and is a member of the tumor necrosis factor (TNF) receptor family. It is expressed not only in sympathetic and sensory neurons, but also in various neural crest cell or tumor derivatives such as melanocytes, melanomas, neuroblastomas, pheochromocytomas, neurofibromas, and neuorotized nevi (type C melanocytes). NGFR has been shown to be a reliable marker for desmoplastic and neurotropic melanoma by several groups. Although the sensitivity of NGFR staining in desmoplastic melanomas has not been systematically analyzed, all reported cases stain with NGFR. A review of 9 cases of desmoplastic melanomas diagnosed in the Dermatopathology Section of the Department of Dermatology at Boston University School of Medicine between 2001 and 2004 disclosed that all 9 cases of desmoplastic melanomas tested stained positively with NGFR. These findings are in contrast to a study reported by Huttenbach et al in which only 33% of their desmoplastic melanomas stained with NGFR. This difference emphasizes the importance of the choice of monoclonal antibody to obtain consistent results. This staining property of desmoplastic melanoma cases, namely early lesions, suspected cases with negative or weak S-100 staining, and those that must be distinguished from a scar.

It is now apparent that expression of NGFR is ubiquitous and not limited to the nervous system, being expressed in mature nonneural cells such as perivascular cells, dental pulp cells, lymphoid follicular dendritic cells, basal epithelium of oral mucosa and hair follicles, prostate basal cells and myoepithelial cells. Unlike the high-affinity nerve growth factor tyrosine kinase receptors (TrkA, TrkB and TrkC), NGFR has no intrinsic tyrosine kinase activity. Studies in prostate and urothelial cancer suggest that NGFR may act as a tumor suppressor, negatively regulating cell growth and proliferation. Anti-NGFR labels the myoepithelial cells of breast ducts and intralobular fibroblasts of breast ducts and thus aids in the diagnosis of malignancy in the breast.

Neurofilament (2F11)

- **Catalog Number:** 760-2661
- **Ordering Code:** 05267714001
- **Quantity:** 50 tests
- **Controls:** Breast, Intestine
- **Isotypes:** IgG1/K
- **Clone Name:** 2F11
- **Species:** Mouse
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

Anti–Neurofilament antibody stains an antigen localized in a number of neural, neuroendocrine, and endocrine tumors. Neuromas, ganglioneuromas, gangliogliomas, ganglioneuroblastomas and neuroblastomas stain positively for neurofilament. Neurofilaments are also present in paragangliomas and adrenal and extra-adrenal pheochromocytomas. Carcinoids, neuroendocrine carcinomas of the skin, and oat cell carcinomas of the lung also express neurofilament.
**Neutrophil Elastase (SP203) Rabbit Monoclonal Primary Antibody**

- **Catalog Number:** 760-4953
- **Ordering Code:** 07391455001
- **Quantity:** 50 tests
- **Controls:** Bone Marrow
- **Isotypes:** IgG
- **Clone Name:** SP203
- **Species:** Rabbit
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Neutrophil Elastase (SP203) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of neutrophils and myeloid precursors within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

**NKX3.1 (EP356) Rabbit Monoclonal Primary Antibody**

- **Catalog Number:** 760-5086
- **Ordering Code:** 07859759001
- **Quantity:** 50 tests
- **Controls:** Prostate, Prostate Adenocarcinoma
- **Isotypes:** IgG
- **Clone Name:** EP356
- **Species:** Rabbit
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**

NKX3.1 (EP356) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the NKX3.1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

**anti-NSE (MRQ-55) Mouse Monoclonal Primary Antibody**

- **Catalog Number:** 760-4786
- **Ordering Code:** 06648568001
- **Quantity:** 50 tests
- **Controls:** Pancreas, Carcinoid Tumor
- **Clone Name:** MRQ-55
- **Species:** Mouse Monoclonal
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque NSE (MRQ-55) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of neuroendocrine neoplasms within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
**Oct-2 (MRQ-2)**

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</table>

**INTENDED USE**

Oct-2 is a transcription factor of the POU homeo-domain family that binds to the Ig gene octamer sites, regulating B-cell-specific genes. These are involved in proliferation and differentiation and despite the scarce evidence for Oct-2 expression in T cells, it has been shown that this factor participates in transcriptional regulation during T-cell activation. Oct-2 activity is dependent on phosphorylation and alternative splicing, although it seems that the level of its expression can be used as a marker of B-cell lineage and differentiation. The following show high levels of Oct-2 expression: germinal center B-cells, mantle B-cells, monocytoïd B-cells, and plasma cells. Various lymphomas are also positive for this marker including the following: B-chronic lymphocytic leukemia, mantle cell lymphoma, follicular lymphoma, marginal zone lymphoma, plasmacytoma, Burkitt lymphoma, diffuse large cell lymphoma, diffuse large B-cell lymphoma, T-cell rich B-cell lymphoma, nodular lymphocyte predominant Hodgkin lymphoma, classic Hodgkin lymphoma.

Several studies of Oct-2 expression have shown a low level expression in pre-B, T-cell, myelomonocytic, and epithelial cell lines, whereas all mature B-cell lines display high levels of expression. Analysis of Oct-2 expression in primary Hodgkin's lymphoma (HLs) and cell lines derived from it showed that the tumor cells analyzed had high levels of expression and activity, suggesting a common B-cell origin for all types of HLs.

Associated products: bcl-6, CD20, CD79a, PAX-5, BOB.1

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**Oct-4 (MRQ-10)**

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<td>Regulatory Status:</td>
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</table>

**INTENDED USE**

Oct-4 is a transcription factor that maintains and regulates pluripotency in embryonic stem and germ cells. It has a very high sensitivity and specificity in seminoma/dysgerminoma and embryonal carcinoma and the germ cell component of gonadoblastoma by nuclear immunostaining. Clear cell carcinoma may enter the differential diagnosis of dysgerminoma as both may grow in nests or tubules, contain clear cells, and have a prominent inflammatory infiltrate (lymphocytes in dysgerminoma and plasma cells in clear cell carcinoma). In one study that looked at Oct-4 staining in clear cell carcinomas, 4 of 14 tumors were found to be focally positive. In another study, 49 endometrioid carcinomas were Oct-4 negative. Rarely dysgerminoma may have a morphologic appearance that overlaps with sex cord-stromal tumors, especially poorly differentiated Sertoli cell tumors. In two studies, however, all sex cord-stromal tumors of the testis and granulose cell tumors of the ovary were Oct-4 negative.

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**Olig2 (EP112) Rabbit Monoclonal Primary Antibody**

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**INTENDED USE**

Olig2 (EP112) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Olig2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
INTENDED USE

p21 is a nuclear 21kD protein, a product of WAF1/CIP1 gene. It is a cyclin-dependent kinase inhibitor 1A (p21, Cip1), also known as CDKN1A, which in humans is encoded by the CDKN1A gene located on chromosome (6p21.2). It is a constituent of a large complex of nuclear proteins, including cyclins, cyclin dependent kinases, and PCNA. Cell cycle progression is regulated by cyclins and their cognate Cdns. p21 inhibits the activity of each member of the cyclin/Cdk family. The expression of this gene acts as an inhibitor of the cell cycle during G1 phase and is tightly controlled by the tumor suppressor protein p53. Normal cells generally display a rather intense nuclear p21 expression. Loss of p21 expression has been associated with poor prognosis in several carcinomas (gastric carcinoma, non-small cell lung carcinoma, thyroid carcinoma).

INTENDED USE

p27 is a cyclin-dependent kinase inhibitor which regulates progression from G1 to S phase by binding and inhibiting cyclin-dependent kinases. Low p27 expression has been associated with unfavorable prognosis in renal cell carcinoma, colon carcinoma, small breast carcinomas, non-small cell lung carcinoma, hepatocellular carcinoma, multiple myeloma, lymph node metastases in Papillary carcinoma of the Thyroid, and more aggressive phenotype in carcinoma of the cervix.

INTENDED USE

Anti-p40 (BC28) Mouse Monoclonal Primary Antibody [anti-p40 (BC28)] is intended for laboratory use in the detection of the p40 protein in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
### anti-p53 (Bp53-11) Primary Antibody

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**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems (Ventana) anti-p53 Primary Antibody (Bp53-11) is a mouse monoclonal antibody directed against both the mutant and wild type of the p53 nuclear phosphoprotein. Very rare normal cells express p53, but alterations in the p53 suppressor gene result in an overproduction of this protein in malignancies. This reagent may be used to aid in the identification of abnormally proliferating cells in neoplastic cell populations. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

### CONFIRM anti-p53 (DO-7) Primary Antibody

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**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems (Ventana) CONFIRM anti-p53 (DO-7) primary antibody is a mouse monoclonal antibody (IgG1, kappa) directed against human p53. The antibody is intended for laboratory use to qualitatively identify by light microscopy wild type and mutant p53 in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

### anti-p57Kip2 (Kp10) Mouse Monoclonal Primary Antibody

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**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque p57Kip2 (Kp10) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. This antibody is used, subsequent to the clinical differential diagnoses of molar pregnancies, as an aid in the recognition of the diseases partial hydatidiform mole, complete hydatidiform, and hydropic abortuses within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
VENTANA anti-p63 (4A4) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4509  
Ordering Code: 05867061001  
Quantity: 50 tests  
Controls: Prostate, Tonsil  
Isotypes: IgG2a/K  
Clone Name: 4A4  
Species: Mouse  
Localization: Nuclear  
Regulatory Status: IVD

INTENDED USE

VENTANA anti-p63 (4A4) Mouse Monoclonal Primary Antibody (VENTANA anti-p63 (4A4)) is directed against the p63 protein. This antibody exhibits a nuclear staining pattern and may be used to aid in the differentiation of benign and malignant prostatic or breast lesions, and in the differentiation of lung squamous cell carcinoma and lung adenocarcinoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

VENTANA anti-p120 catenin (98) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4517  
Ordering Code: 05867088001  
Quantity: 50 tests  
Controls: Normal Ducts of the Breast  
Isotypes: IgG1  
Clone Name: 98  
Species: Mouse  
Localization: Membranous (ductal), Cytoplasmic (lobular)  
Regulatory Status: IVD

INTENDED USE

VENTANA anti-p120 catenin (98) Mouse Monoclonal Primary Antibody is directed against human juxtamembrane protein p120 expressed as a part of the cell-cell adhesion complex in epithelial tissues. Cytoplasmic accumulation of p120 is associated with lobular breast carcinoma whereas ductal neoplasms retain membranous localization. This antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody

Catalog Number: 760-2135  
Ordering Code: 05266840001  
Quantity: 250 tests  
Controls: Intestine, Liver  
Isotypes: IgG1  
Clone Name: AE1/AE3 & PCK26  
Species: Mouse  
Localization: Cytoplasmic  
Regulatory Status: IVD

INTENDED USE

Anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody (Anti-Pan Keratin (AE1/AE3/PCK26) is a cocktail of antibodies directed against keratins present in simple and complex epithelial cells. This product exhibits a cytoplasmic staining pattern and may be used to aid in the identification of normal and abnormal epithelial cells, and as an aid in determining tumor lineage. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
Parathyroid Hormone (PTH) (MRQ-31) 
**Mouse Monoclonal Antibody**

- **Catalog Number:** 760-4532
- **Ordering Code:** 06419224001
- **Quantity:** 50 tests
- **Controls:** Parathyroid
- **Isotypes:** IgG2a
- **Clone Name:** MRQ-31
- **Species:** Mouse
- **Localization:** Cytoplasmic, Membranous
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque anti-Parathyroid Hormone (PTH) (MRQ-31) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using VENTANA BenchMark® automated IHC test methods. Use of this antibody is indicated as an aid in diagnostic determination of the identification of parathyroid glands within the context of an antibody panel, the patient’s clinical history and other diagnostic tests evaluated by a qualified pathologist or physician.

PAX-8 (MRQ-50)

- **Catalog Number:** 760-4618
- **Ordering Code:** 06523927001
- **Quantity:** 50 tests
- **Controls:** Thyroid Carcinoma, Ovarian Carcinoma (Non-Mucinous Carcinoma)
- **Isotypes:** IgG
- **Clone Name:** MRQ-50
- **Species:** Mouse
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque PAX8 (MRQ-50) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of renal cell carcinoma, thyroid carcinoma, and ovarian carcinoma within the context of antibody panels, the patient’s clinical history and other diagnostic tests evaluated by a qualified pathologist.

CONFIRM anti-PAX5 (SP34) Rabbit Monoclonal Primary Antibody

- **Catalog Number:** 790-4420
- **Ordering Code:** 05552729001
- **Quantity:** 50 tests
- **Controls:** Spleen, Tonsil
- **Clone Name:** SP34
- **Species:** Rabbit
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM antiPAX5 (SP34) Rabbit Monoclonal Primary Antibody is directed against a nuclear epitope present in human B lymphocytes. This antibody may be used to aid in the identification of normal and neoplastic cells of B-lymphocytic lineage. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining, or the absence of staining, shall be complemented by morphological studies and evaluation of proper controls. Evaluation shall be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.
**PD-1 (NAT105) Mouse Monoclonal Antibody**

**Catalog Number:** 760-4895  
**Ordering Code:** 07099029001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Tonsil  
**Isotypes:** IgG  
**Clone Name:** NAT105  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque PD-1 (NAT105) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of T-cell lymphoma within the context of antibody panels, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.

**VENTANA PD-L1 (SP142) Assay**

**Catalog Number:** 740-4859  
**Ordering Code:** 07709374001  
**Quantity:** 50 tests  
**Controls:** Tonsil  
**Clone Name:** SP142  
**Species:** Rabbit  
**Localization:** Membranous and/or Cytoplasmic Staining  
**Regulatory Status:** IVD

**INTENDED USE**

VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma and non-small cell lung cancer (NSCLC) tissue stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a VENTANA BenchMark ULTRA instrument. Determination of PD-L1 status is indication-specific, and evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity. PD-L1 expression in ≥ 5% IC determined by VENTANA PD-L1 (SP142) Assay in urothelial carcinoma tissue is associated with increased objective response rate (ORR) in a nonrandomized study of TECENTRIQ (atezolizumab). PD-L1 expression in ≥ 50% TC or ≥ 10% IC determined by VENTANA PD-L1 (SP142) Assay in NSCLC tissue may be associated with enhanced overall survival from TECENTRIQ (atezolizumab). This product is intended for in vitro diagnostic (IVD) use.

**VENTANA PD-L1 (SP263) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 790-4905  
**Ordering Code:** 07494190001  
**Quantity:** 50 tests  
**Controls:** Placenta  
**Isotypes:** IgG  
**Clone Name:** SP263  
**Species:** Rabbit  
**Localization:** Membranous and/or Cytoplasmic Staining  
**Regulatory Status:** IVD

**INTENDED USE**

VENTANA PD-L1 (SP263) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the PD-L1 protein in formalin-fixed, paraffin-embedded tissue. It is intended to be stained with the VENTANA BenchMark ULTRA immunohistochemical automated slide stainer. It is indicated as an aid in the assessment of PD-L1 expression in non-small cell lung cancer (NSCLC) and other tumor types. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
### PRIMARY ANTIBODIES

#### Perforin (MRQ-23)

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**INTENDED USE**

Perforin is a pore-forming protein that leads to osmotic lysis of the target cells and subsequently enables granzymes to enter the target cells and activate apoptosis, the cell death program. The expression of perforin is upregulated in activated CD8+ T cells, but in NK cells the expression is constitutively very high and stable. Perforin expression can also be stimulated in some activated CD4+ T cells. CD8+ T cells and NK cells use both the perforin/granzyme and the Fas/FasL pathways, while CD4+ T cells preferentially use the Fas/FasL pathway. Although some investigators report a cytolytic potential of CD4+ T cells, it appears more likely that CD8+ T cells are the major effector population in Th1- associated inflammatory skin diseases. The role of perforin-mediated cytotoxicity has been demonstrated in various autoimmune diseases. In vitro and in vivo studies suggest that the cytotoxicity of CTLs may be mediated by cytotoxic granules in certain inflammatory diseases in humans. In addition, it seems that T-cell cytotoxicity against keratinocytes is mediated by perforin in some inflammatory skin diseases. Other authors suggest that perforin may have a dual role in alloimmune response (organ transplant applications). In one regard, it has a cytolytic function in acute rejection, and, in contrast, it may be responsible for downregulating both CD4- and CD8-mediated alloimmune response.

#### PGP 9.5 Rabbit Polyclonal Antibody

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque PGP 9.5 (Polyclonal) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of mesenchymal neoplasms within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

#### Phosphohistone H3 (PHH3)

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**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Phosphohistone H3 (PHH3) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in identification of mitotic activity in tumor cells and diagnosis of tumor grade differentiation within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
INTENDED USE

Anti-PLAP antibody immunoreacts with germ cell tumors and can discriminate between these and other neoplasms. Somatic neoplasms e.g. breast, gastrointestinal, prostatic and urinary cancers may also immunoreact with antibodies to PLAP. Anti-PLAP positivity in conjunction with keratin negativity favors seminoma over carcinoma. Germ cell tumors are usually keratin positive, but they regularly fail to stain with anti-EMA, whereas most carcinomas stain with anti-EMA. Anti-PLAP has been useful in the diagnosis of gestational trophoblastic disease. This antibody has shown cross-reaction with human intestinal alkaline phosphatase.

PMS2 (EPR3947) Rabbit Monoclonal Antibody

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque PMS2 (EPR3947) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of MSI-H tumors within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

Podoplanin (D2-40) Mouse Monoclonal Antibody

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Podoplanin (D2-40) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of lymphatic invasion of a variety of tumors and between epitheloid and mesothelioma and lung adenocarcinoma within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
CONFIRM anti-Progesterone Receptor (PR) (1E2)
Rabbit Monoclonal Primary Antibody

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**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal (IgG) is intended for laboratory use for the qualitative detection of progesterone receptor (PR) antigen in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM antiPR (1E2) is directed against an epitope present on human progesterone receptor protein located in the nucleus of PR positive normal and neoplastic cells. CONFIRM anti-PR (1E2) is indicated as an aid in the management, prognosis, and prediction of therapy outcome of breast carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. Prescription use only.

Prolactin (polyclonal)

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**INTENDED USE**
Anti-Prolactin is a useful marker in classification of pituitary tumors and the study of pituitary disease. It reacts with prolactin-producing cells. Such prolactin-producing cells can also be found in prostate epithelium.

CONFIRM anti-Prostate Specific Antigen (PSA)
Rabbit Polyclonal Primary Antibody

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**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Prostate Specific Antigen (PSA) Primary Antibody is a rabbit polyclonal antibody (Ig) directed against both free and bound human prostate specific antigen (PSA). This antibody is intended for use to qualitatively identify PSA by light microscopy in sections of formalin-fixed, paraffin-embedded tissue following staining on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.
**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque PSA (ER-PR8) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of prostatic adenocarcinoma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

**PSAP (PASE/4LJ)**

Anti-PSAP reacts with prostatic acid phosphatase in the glandular epithelium of normal and hyperplastic prostate, carcinoma of the prostate, and metastatic cells of prostatic carcinoma. This marker may be helpful in pinpointing the site of origin in cases of metastatic carcinoma of the prostate, and is considered a more sensitive marker than PSA. However, it also offers less specificity. Nevertheless, PSAP complements PSA in the right clinical context.

**VENTANA PTEN (SP218) Rabbit Monoclonal Primary Antibody**

The VENTANA PTEN (SP218) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative detection of the phosphatase and tensin homolog (PTEN) protein in formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This antibody is intended for in vitro diagnostic (IVD) use.
**Rabbit Monoclonal Negative Control Ig**

**Catalog Number:** 790-4795  
**Ordering Code:** 06883380001  
**Quantity:** 250 tests  
**Controls:** Test Positive Tissue  
**Isotypes:** IgG  
**Species:** Rabbit  
**Regulatory Status:** IVD

**INTENDED USE**

Rabbit Monoclonal Negative Control Ig is intended for laboratory use as a control for nonspecific binding of rabbit immunoglobulin in sections of formalin-fixed, paraffin-embedded tissue when stained on VENTANA BenchMark IHC/ISH platforms (BenchMark GX, BenchMark XT, and BenchMark ULTRA). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

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**Renal Cell Carcinoma (PN-15)**

**Catalog Number:** 760-4273  
**Ordering Code:** 05269369001  
**Quantity:** 50 tests  
**Controls:** Kidney, Renal Cell Carcinoma  
**Isotypes:** IgG1/K  
**Clone Name:** PN-15  
**Species:** Mouse  
**Localization:** Cytoplasmic, Membranous  
**Regulatory Status:** IVD

**INTENDED USE**

Anti-Renal Cell Carcinoma (PN-15) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Renal Cell Carcinoma protein in formalin-fixed, paraffin-embedded neoplastic tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

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**CONFIRM anti-S100 (4C4.9) Primary Antibody**

**Catalog Number:** 790-2914  
**Ordering Code:** 05278104001  
**Quantity:** 50 tests  
**Controls:** Melanoma  
**Isotypes:** IgG2a  
**Clone Name:** 4C4.9  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems’ (Ventana) CONFIRM anti-S100 (4C4.9) Primary Antibody is a mouse monoclonal antibody (IgG2a) directed against S100 protein. The antibody is intended for use to qualitatively identify S100 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests. Prescription only.
CONFIRM anti–S100 (Polyclonal) Primary Antibody

Catalog Number: 760-2523
Ordering Code: 05267072001
Quantity: 50 tests
Controls: Melanoma
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems, Inc.’s (Ventana) CONFIRM anti–S100 (Polyclonal) Primary Antibody contains rabbit antiserum directed against an epitope found on S100 protein and may be used to aid in the identification of cells of normal and abnormal neuronal and neuroendocrine lineage and as an aid in the diagnosis of anaplastic tumors. The antibody is intended for qualitative staining in section of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

SALL4 (6E3) Mouse Monoclonal Primary Antibody

Catalog Number: 760-4864
Ordering Code: 07047690001
Quantity: 50 tests
Controls: Seminoma
Isotypes: IgG
Clone Name: 6E3
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque SALL4 (6E3) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue using IHC test methods. Use of this antibody is indicated as an aid in the identification of germ cell neoplasms within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.

Smoothelin (R4A) Mouse Monoclonal Antibody

Catalog Number: 760-4592
Ordering Code: 06433278001
Quantity: 50 tests
Controls: Bladder, Leiomyosarcoma
Isotypes: IgG1
Clone Name: R4A
Species: Mouse Monoclonal
Localization: Cytoplasmic (MP), Nuclear
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Smoothelin (R4A) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated as an aid in the distinction of terminally differentiated smooth muscle cells, smooth muscle neoplasms of the gastrointestinal tract and other organs, and staging of bladder carcinoma within the context of an antibody panel, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.
**Somatostatin (polyclonal)**

**Catalog Number:** 760-2667  
**Ordering Code:** 05267781001  
**Quantity:** 50 tests  
**Controls:** Pancreas  
**Clone Name:** Polyclonal  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
Anti-Somatostatin is a useful marker of D-cells of pancreatic islet cells. D-cells identification can be used to identify hyperplasia of the pancreatic islets as well as islet cell tumors such as somatostatinomas. Somatostatin can also be found in gastrointestinal and bronchopulmonary endocrine cells, thymic endocrine cells, and thyroid C cells. Somatostatin suppresses gastric acid secretion, gallbladder contractions, and pancreatic enzyme secretion.

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**SOX-2 (SP76)**

**Catalog Number:** 760-4621  
**Ordering Code:** 065239A3001  
**Quantity:** 50 tests  
**Controls:** Squamous Epithelium  
**Isotypes:** IgG  
**Clone Name:** SP76  
**Species:** Rabbit  
**Localization:** Nuclear  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque SOX-2 (SP76) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of lung squamous cell carcinoma and germ cell tumors within the context of antibody panels, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**SOX-10 (SP267) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 760-4988  
**Ordering Code:** 07560389001  
**Quantity:** 50 tests  
**Controls:** Melanoma, Skin Melanocytes  
**Isotypes:** IgG  
**Clone Name:** SP267  
**Species:** Rabbit  
**Localization:** Nuclear  
**Regulatory Status:** IVD

**INTENDED USE**
SOX-10 (SP267) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the SOX-10 protein in formalin-fixed, paraffin-embedded tissue stained on BenchMark immunohistochemical (IHC/ISH) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque SOX-11 (MRQ-58) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification and differentiation of mantle cell lymphomas within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

**Spectrin (RBC2/3D5)**
- **Catalog Number:** 760-4274
- **Ordering Code:** 05269377001
- **Quantity:** 50 tests
- **Controls:** Bone Marrow
- **Isotypes:** IgG2a/K
- **Clone Name:** RBC2/3D5
- **Species:** Mouse
- **Localization:** Membranous
- **Regulatory Status:** IVD

**INTENDED USE**
Spectrin is a cytoskeletal protein which is found in muscles, red blood cells and red cell precursors. Anti-Spectrin antibody is useful in the diagnosis of erythroid leukemias.

**Synaptophysin (MRQ-40)**
- **Catalog Number:** 760-4595
- **Ordering Code:** 06433324001
- **Quantity:** 50 tests
- **Controls:** Pancreatic Islet Cells
- **Isotypes:** IgG1
- **Clone Name:** MRQ-40
- **Species:** Rabbit Monoclonal
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque Synaptophysin (MRQ-40) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. This antibody is used as an aid in the identification of neuroendocrine neoplasms within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
CONFIRM anti-Synaptophysin (SP11) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4407
Ordering Code: 05479304001
Quantity: 50 tests
Controls: Pancreas
Clone Name: SP11
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM antiSynaptophysin (SP11) Rabbit Monoclonal Primary Antibody is designed to qualitatively detect the presence of synaptophysin expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue. Positive staining results may aid in the classification of neuroendocrine tumors. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

T-bet (MRQ-46) Rabbit Monoclonal Antibody

Catalog Number: 760-4598
Ordering Code: 06433391001
Quantity: 50 tests
Controls: Hairy Cell Leukemia, Tonsil
Isotypes: IgG
Clone Name: MRQ-46
Species: Rabbit Monoclonal
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque T-bet (MRQ-46) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of hairy cell leukemia, Hodgkin lymphoma, and precursor B-cell lymphoblastic leukemia/lymphoma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

TAG-72 (B72.3)

Catalog Number: 760-2669
Ordering Code: 05267803001
Quantity: 50 tests
Controls: Breast Carcinoma
Isotypes: IgG/K
Clone Name: B72.3
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
Anti-TAG-72 (B72.3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the TAG-72 protein in formalin-fixed, paraffin-embedded neoplastic tissue stained on VENTANA BenchMark immunohistochemical (IHC) automated slide stainers. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque TdT antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of lymphomas within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**anti-TFE3 (MRQ-37) Rabbit Monoclonal Primary Antibody**

- **Catalog Number:** 760-4622
- **Ordering Code:** 06523951001
- **Quantity:** 50 tests
- **Controls:** Testis (Germ Cells), XP11.2 Translocation Renal Cell
- **Isotypes:** IgG
- **Clone Name:** MRQ-37
- **Species:** Rabbit
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque TFE3 (MRQ-37) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated subsequent to the clinical diagnosis of malignancy as an aid in the recognition of Xp11 translocation renal cell carcinoma and alveolar soft part sarcoma within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

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**CONFIRM anti-Thymidine Phosphorylase (P-GF.44C) Mouse Monoclonal Primary Antibody**

- **Catalog Number:** 790-4454
- **Ordering Code:** 05976502001
- **Quantity:** 50 tests
- **Controls:** See Package Insert
- **Isotypes:** IgG1
- **Clone Name:** P-GF.44C
- **Species:** Mouse
- **Localization:** Nuclear, Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-Thymidine Phosphorylase (PGF.44C) Mouse Monoclonal Primary Antibody recognizes human thymidine phosphorylase, an angiogenic factor, expressed in varying levels by macrophages, stromal cells, glial cells and some epithelial cells. Thymidine phosphorylase shows a cytoplasmic and/or nuclear location. This antibody exhibits a nuclear and/or cytoplasmic staining pattern and may be used to aid in the detection of thymidine phosphorylase in carcinoma of the breast, esophagus, stomach, colon and rectum, pancreas, head and neck, ovaries and lung. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
PRIMARY ANTIBODIES

Thyroglobulin (2H11+ 6E1)

- **Catalog Number:** 760-2671
- **Ordering Code:** 05267620001
- **Quantity:** 50 tests
- **Controls:** Thyroid
- **Isotypes:** IgG1
- **Clone Name:** 2H11+6E1
- **Species:** Mouse
- **Localization:** Cytoplasmic
- **Regulatory Status:** IVD

**INTENDED USE**

Anti-Thyroglobulin antibody reacts with human thyroglobulin as demonstrated by a single band of immunoblotting in a lysate of human thyroid tissue. The vast majority of follicular carcinomas of the thyroid will give positive immunoreactivity for thyroglobulin even though sometimes only focal. Poorly differentiated carcinomas of the thyroid are frequently thyroglobulin negative. Adenocarcinomas of other than thyroid origin do not react with this antibody.

CONFIRM anti-Thyroid Transcription Factor-1 (8G7G3/1) Mouse Monoclonal Primary Antibody

- **Catalog Number:** 790-4398
- **Ordering Code:** 05479312001
- **Quantity:** 50 tests
- **Controls:** Lung, Thyroid, Lung Carcinoma
- **Isotypes:** IgG
- **Clone Name:** 8G7G3/1
- **Species:** Mouse
- **Localization:** Nuclear
- **Regulatory Status:** IVD

**INTENDED USE**

CONFIRM anti-Thyroid Transcription Factor-1 (8G7G3/1) Mouse Monoclonal Primary Antibody (CONFIRM anti-Thyroid Transcription Factor-1 (8G7G3/1)) is designed to qualitatively detect the presence of thyroid transcription factor-1 (TTF-1) expressing cells. TTF-1 positive staining results may aid in the classification of neoplasms of the lung and thyroid. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. The antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody

- **Catalog Number:** 790-4756
- **Ordering Code:** 06640613001
- **Quantity:** 50 tests
- **Controls:** Normal Thyroid, Lung Carcinoma, Normal Lung
- **Isotypes:** IgG
- **Clone Name:** SP141
- **Species:** Rabbit
- **Localization:** Nuclear
- **Regulatory Status:** IVD
- **Alternate Names:** Thyroid Transcription Factor - 1

**INTENDED USE**

Anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody (anti-TTF-1 (SP141)) is directed against the thyroid transcription factor-1 (TTF-1) protein. This antibody exhibits a nuclear staining pattern and may be used to aid in the classification of neoplasms of the lung and thyroid. This antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
CONFIRM anti-Topoisomerase IIα (JS5B4) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4371
Ordering Code: 05479339001
Quantity: 50 tests
Controls: Spleen, Tonsil
Clone Name: JS5B4
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' CONFIRM anti-Topoisomerase IIα (JS5B4) Rabbit Monoclonal Primary Antibody is designed to qualitatively detect the presence of topoisomerase IIα expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue following staining on a Ventana BenchMark XT instrument. During the cell cycle, topoisomerase IIα is expressed in the G1, S, G2, and M phase but is absent in the G0 (quiescent) phase. Assessment of the proportion of positive staining cells for topoisomerase IIα may aid in evaluation of the proliferative activity of normal and/or neoplastic tissue. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.


CONFIRM anti-Total c-MET (SP44) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4430
Ordering Code: 05571219001
Quantity: 50 tests
Controls: Kidney, Non-Small Cell Lung Carcinoma, Gastric Carcinoma
Clone Name: SP44
Species: Rabbit
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems' (Ventana) CONFIRM anti-Total c-MET (SP44) Rabbit Monoclonal Primary Antibody is directed against a membranous and/or cytoplasmic epitope present in human normal epithelial or tumor cells. This antibody may be used to aid in the identification of normal and neoplastic c-MET expressing cells. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This antibody is intended for in vitro diagnostic (IVD) use.
TRAcP (9C5) Mouse Monoclonal Primary Antibody

**Catalog Number:** 760-4275  
**Ordering Code:** 05269385001  
**Quantity:** 50 tests  
**Controls:** Hairy Cell Leukemia  
**Isotypes:** IgG2b  
**Clone Name:** 9C5  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque TRAcP (9C5) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of Hairy Cell Leukemia within the context of antibody panels, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.

Tryptase (G3)

**Catalog Number:** 760-4276  
**Ordering Code:** 05269393001  
**Quantity:** 50 tests  
**Controls:** Mast Cell-Containing Tissue  
**Isotypes:** IgG1  
**Clone Name:** G3  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
Tryptases constitute a subfamily of trypsin-like proteinases, stored in the mast cell secretory granules and basophils. Upon cellular activation, these enzymes are released into the extracellular environment. Anti-tryptase is a good marker for mast cells, basophils, and their derivatives.

TSH (polyclonal)

**Catalog Number:** 760-2709  
**Ordering Code:** 05268184001  
**Quantity:** 50 tests  
**Controls:** Normal Pituitary  
**Clone Name:** Polyclonal  
**Species:** Rabbit  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
Anti-TSH is a useful marker in classification of pituitary tumors and the study of pituitar disease. It reacts with TSH-producing cells (thyrotrophs).
CONFIRM anti-Tyrosinase (T311) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4365
Ordering Code: 05479347001
Quantity: 50 tests
Controls: Lung, Melanoma
Isotypes: IgG 2a
Clone Name: T311
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic use. Ventana Medical Systems’ CONFIRM® anti-Tyrosinase (T311) Mouse Monoclonal Primary Antibody is designed to qualitatively detect the presence of tyrosinase expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. Positive results aid in the classification of melanoma. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

Uroplakin III (SP73) Rabbit Monoclonal Antibody

Catalog Number: 760-4533
Ordering Code: 06419232001
Quantity: 50 tests
Controls: Bladder
Isotypes: IgG 1
Clone Name: SP73
Species: Rabbit
Localization: Membranous, Cytoplasmic
Regulatory Status: IVD

INTENDED USE
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque anti-Uroplakin III (SP73) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using VENTANA BenchMark® automated IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases as an aid in the identification of transitional cell carcinoma within the context of antibody panels, the patient’s clinical history, and other diagnostic tests evaluated by a qualified pathologist.

Villin (CWWB1)

Catalog Number: 760-4277
Ordering Code: 05269407001
Quantity: 50 tests
Controls: Colonic Mucosa, Small Bowel Mucosa
Isotypes: IgG 1
Clone Name: CWWB1
Species: Mouse
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

INTENDED USE
Villin is a 95-kD glycoprotein of microvilli associated with rootlet formation in gastrointestinal mucosal epithelium. Anti-Villin labels the brush border area in the gastrointestinal mucosal epithelium. This antibody has been useful in differentiating gastrointestinal adenocarcinoma, neuroendocrine carcinomas and ovarian adenocarcinomas from adenocarcinomas from other organs. Also labeled by this antibody are Merkel cells of the skin.
CONFIRM anti-Vimentin (V9)
Primary Antibody

**Catalog Number:** 790-2917  
**Ordering Code:** 05278139001  
**Quantity:** 50 tests  
**Controls:** Lymph Node, Skin  
**Isotypes:** IgG/K  
**Clone Name:** V9  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Vimentin (V0) Primary Antibody is a mouse monoclonal antibody (IgG1) directed against vimentin. This antibody is intended for use to qualitatively identify vimentin by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

CONFIRM anti-Vimentin (Vim 3B4)
Primary Antibody

**Catalog Number:** 760-2512  
**Ordering Code:** 05266998001  
**Quantity:** 50 tests  
**Controls:** Intestine, Liver  
**Isotypes:** IgG 2a  
**Clone Name:** Vim 3B4  
**Species:** Mouse  
**Localization:** Cytoplasmic  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Vimentin (Vim 3B4) is a mouse monoclonal antibody directed against purified bovine eye lens vimentin and has been known to react specifically with human vimentin. This reagent should be used with a panel of antibodies to aid in the immunohistochemical identification of cells of normal and abnormal mesenchymal lineage as an aid in diagnosis of anaplastic tumors in formalin-fixed, paraffin-embedded tissue. CONFIRM anti-Vimentin (Vim 3B4) binds specifically with the 57kD intermediate filament protein, vimentin. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

WT1 (6F-H2)

**Catalog Number:** 760-4397  
**Ordering Code:** 05435706001  
**Quantity:** 50 tests  
**Controls:** Kidney, Testicle, Malignant Mesothelioma  
**Isotypes:** IgG1/K  
**Clone Name:** 6F-H2  
**Species:** Mouse  
**Localization:** Nuclear  
**Regulatory Status:** IVD

**INTENDED USE**
This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque WT1 (6F-H2) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of WT1 protein over-expression in mesothelioma, ovarian carcinoma and Wilm's tumor within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
ZAP-70 (2F3.2)

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</table>

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque ZAP-70 (2F3.2) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of ZAP-70 protein expressing chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.
Detection Systems

Innovation

Delivering solutions that change the practice of medicine and improve patient care
OptiView DAB IHC Detection
Innovative detection for enhanced stain quality

Powered by proprietary hapten technology, the dynamic range of VENTANA OptiView DAB IHC detection delivers unparalleled sensitivity and specificity so you can detect antigens across a wide range of expression levels. Virtually eliminating background even as signal intensity increases, OptiView chemistry provides the quality, flexibility and speed you need to deliver results quickly and confidently for enhanced patient care.

- **Increase sensitivity:** By increasing the numbers of HRP enzymes at each primary antibody site, OptiView chemistry provides unparalleled signal intensity, empowering you to visualize even low-level markers.

- **Improve specificity:** Our patented synthetic, non-endogenous hapten system eliminates the potential for species-to-species interactions, which frequently cause background.

- **Customize intensity:** Unique chemistry and flexibility in protocol optimization enable greater control to meet your preferred staining intensity.

- **Improve turnaround time:** Enhanced sensitivity and software flexibility allow you to reduce turn-around time by 30 minutes or more for most assays, giving you the ability to process more slides in less time and deliver results sooner.

**OptiView detection chemistry: our unique formula for success**

Featuring a two-step design and unique synthetic, non-endogenous hapten technology on the secondary antibody, OptiView detection provides excellent background reduction. In addition, it delivers increased sensitivity through a higher number of multimers per primary antibody. The reaction is further enhanced by a proprietary reagent that accelerates DAB color development in the presence of the HRP enzyme.

Feature stains: Cyclin D1 (SP4) on mantle cell lymphoma with OptiView DAB IHC Detection Kit (left) and with OptiView detection plus OptiView Amplification Kit (right).
VENTANA ancillary products for amplification

**Amplification Kit**
Catalog Number: 760-080  
Ordering Code: 05266114001  
Quantity: 100 tests  
Regulatory Status: IVD

Ventana Medical Systems, Inc.’s (Ventana) Amplification Kit may be used in conjunction with VENTANA detection kits to increase the signal intensity of weak staining mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, frozen tissue or cytological preparations on VENTANA automated side stainers with VENTANA primary antibodies, detection kits and ancillary reagents.

The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

This product is intended for in vitro diagnostic (IVD) use.

**OptiView Amplification Kit (50)**
Catalog Number: 760-099  
Ordering Code: 06396518001  
Quantity: 50 tests  
Regulatory Status: IVD

OptiView Amplification Kit may be used in conjunction with the OptiView DAB IHC Detection Kit (OptiView Detection Kit) to increase the staining intensity of mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, frozen tissue, or cytological preparations on VENTANA BenchMark Advanced Staining automated slide stainers with VENTANA primary antibodies and ancillary reagents, visualized by light microscopy.

The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

This product is intended for in vitro diagnostic (IVD) use.

**OptiView Amplification Kit (250)**
Catalog Number: 760-099  
Ordering Code: 06718663001  
Quantity: 250 tests  
Regulatory Status: IVD
iVIEW DAB Detection Kit

Catalog Number: 760-091
Ordering Code: 05266157001
Quantity: 250 tests
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems' (Ventana) iVIEW DAB Detection Kit is an indirect biotin streptavidin system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended for laboratory use to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded and frozen tissue on BenchMark and BenchMark XT instruments by light microscopy.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This product is intended for in vitro diagnostic (IVD) use.

OptiView DAB IHC Detection Kit

Catalog Number: 760-700
Ordering Code: 08396500001
Quantity: 250 tests
Regulatory Status: IVD

INTENDED USE
OptiView DAB IHC Detection Kit (OptiView) is an indirect, biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded and frozen tissue that are stained on the VENTANA automated slide stainers and visualized by light microscopy. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This product is intended for in vitro diagnostic (IVD) use.

ultraView Universal Alkaline Phosphatase Red Detection Kit

Catalog Number: 760-501
Ordering Code: 05269814001
Quantity: 250 tests
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems' (Ventana) ultraView Universal Alkaline Phosphatase Red Detection Kit is an indirect, biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded and frozen tissue that are stained on the Ventana BenchMark Series instruments including BenchMark, BenchMark XT, and BenchMark ULTRA automated slide stainers. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

This detection kit is intended for in vitro diagnostic use.
ultraView Universal DAB Detection Kit

Catalog Number: 760-500
Ordering Code: 05269806001
Quantity: 250 tests
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems’ (Ventana) ultraView Universal DAB Detection Kit is an indirect, biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded and frozen tissue that are stained on the BenchMark, BenchMark XT, and BenchMark ULTRA instruments.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This product is intended for in vitro diagnostic (IVD) use.

ultraVIEW SISH Detection Kit

Catalog Number: 780-001
Ordering Code: 05271967001
Quantity: 100 tests
Regulatory Status: IVD

INTENDED USE
This detection kit is intended for in vitro diagnostic use.

Ventana Medical Systems’ (Ventana) ultraView SISH Detection Kit is an indirect, biotin-free system for detecting rabbit primary antibodies. The kit is intended to identify targets by in situ hybridization (ISH) in sections of formalin-fixed, paraffin-embedded tissue that are stained on the BenchMark Series automated slide stainers. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient’s clinical history and other diagnostic tests.

ISH iVIEW Blue Plus Detection Kit

Catalog Number: 760-097
Ordering Code: 05266181001
Quantity: 100 tests
Regulatory Status: IVD

INTENDED USE
Ventana Medical Systems, Inc.’s (Ventana) ISH iVIEW Blue Plus Detection Kit consists of a primary rabbit anti-DNP antibody followed by an indirect biotin streptavidin system for detecting VENTANA DNP labeled probes and antibodies. This kit is intended for staining sections of routinely fixed (neutral buffered formalin), paraffin-embedded tissue on the BenchMark Series automated slide stainers.

Light microscopy is used to detect the staining intensity. Positive results aid in the classification of normal and abnormal cells and tissues and serve as an adjunct to conventional histopathology tests.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This reagent is intended for in vitro diagnostic (IVD) use.
**ultraView Red ISH DIG Detection Kit**

- **Catalog Number:** 760-505
- **Ordering Code:** 05587778001
- **Quantity:** 100 tests
- **Regulatory Status:** IVD

**INTENDED USE**

Ventana Medical Systems, Inc.'s (Ventana) ultraView Red ISH DIG Detection Kit is an indirect, biotin-free system for detecting DIG labeled probes. The kit is intended to identify targets by chromogenic red in situ hybridization (ISH) in sections of formalin-fixed, paraffin-embedded tissue that are stained on VENTANA BenchMark XT automated slide stainer or VENTANA BenchMark ULTRA automated slide stainer.

The clinical interpretation of any staining, or the absence of staining, must be complemented by histological examination and evaluation of proper controls. Evaluation must be made by a qualified reader within the context of the patient's clinical history and other diagnostic tests.

This detection kit is intended for in vitro diagnostic (IVD) use.

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**ultraView SISH DNP Detection Kit**

- **Catalog Number:** 760-098
- **Ordering Code:** 05572037001
- **Quantity:** 100 tests
- **Regulatory Status:** IVD

**INTENDED USE**

Ventana Medical Systems, Inc.'s (Ventana) ultraView SISH DNP Detection Kit is an indirect, biotin-free system for detecting DNP labeled probes. The kit is intended to identify targets by silver in situ hybridization (ISH) in sections of formalin-fixed, paraffin-embedded tissue that are stained on VENTANA BenchMark XT automated slide stainer or VENTANA BenchMark ULTRA automated slide stainer instruments.

The clinical interpretation of any staining, or the absence of staining, must be complemented by histological examination and evaluation of proper controls. Evaluation must be made by a qualified reader within the context of the patient's clinical history and other diagnostic tests.

This detection kit is intended for in vitro diagnostic (IVD) use.
Dedication

Committed to providing automated solutions for consistent high-quality stains
The VENTANA BenchMark Special Stains system empowers histopathology labs with reproducible, high-quality staining capabilities through ready-to-use, quality-controlled reagents. You can count on consistent staining—run to run, slide to slide, day to day—supporting fast, accurate results. With flexible protocols, you can employ a broad range of options to achieve your desired staining results.

**Quality**
- Count on consistent staining through ready-to-use kits that provide high-quality stains.

**Safety**
- Reduce risk and technicians’ exposure to harmful chemicals through ready-to-use staining kits.

**Workflow**
- Increase efficiency and turnaround time with ready-to-use kits that eliminate manual reagent preparation, freeing staff for value-added activities.
### VENTANA Special Stains System Selection Guide

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<td>Alcian Blue for PAS</td>
<td>Light Green for PAS</td>
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<td>Mucicarmine Staining Kit</td>
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- **For use on the VENTANA BenchMark Special Stains system.**
- **For use on the VENTANA NexES Special Stains system.** Instrument no longer available.
Special Staining Kits for Mucin

**Alcian Blue for PAS**

- **Catalog Number:** 860-003
- **Ordering Code:** 05279194001
- **Quantity:** 75 tests
- **Controls:** Colon, Salivary Gland, Small Intestine

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Alcian Blue for PAS Staining Kit, in conjunction with the PAS Staining Kit (860-014 / 05279291001), is intended for use as a qualitative histologic stain to differentiate acid mucin from neutral polysaccharides in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

**Alcian Blue Staining Kit**

- **Catalog Number:** 860-002
- **Ordering Code:** 05279186001
- **Quantity:** 75 tests
- **Controls:** Colon, Small Intestine

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Alcian Blue Staining Kit is intended for in vitro diagnostic (IVD) use as a qualitative histologic stain to demonstrate weakly acidic mucopolysaccharides. At pH 2.5, alcian blue stains sulfated and carboxylated acid mucopolysaccharides and sulfated and carboxylated sialomucins and glycoproteins in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

**Diastase Kit**

- **Catalog Number:** 860-004
- **Ordering Code:** 05279208001
- **Quantity:** 75 tests
- **Controls:** Liver

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Diastase Kit, in conjunction with PAS Staining Kit (860-014 / 05279291001), is intended for use as a digestion reagent to aid in the determination of glycogen in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.
**Light Green for PAS**

Catalog Number: 860-010  
Ordering Code: 05279267001  
Quantity: 75 tests  
Controls: Liver

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Light Green for PAS used in conjunction with PAS Staining Kit is intended for use as a qualitative histologic stain for detection of fungus in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

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**Mucicarmine Staining Kit**

Catalog Number: 860-011  
Ordering Code: 05279275001  
Quantity: 75 tests  
Controls: Human Tissue with Epithelial Mucin

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Mucicarmine Staining Kit is intended for use as a qualitative histologic stain to detect acid mucopolysaccharides (mucin) in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

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**PAS Staining Kit**

Catalog Number: 860-014  
Ordering Code: 05279291001  
Quantity: 75 tests  
Controls: Tissue Known to be Glycogen Rich, such as Kidney, Small Intestine, Liver, Skin, or Aorta

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

PAS Staining Kit is intended for use as a qualitative histologic stain used to demonstrate the presence of glycogen in formalin-fixed, paraffin-embedded tissue. PAS Staining Kit detects positive reticular fibers, basement membrane, fungus, and neutral mucopolysaccharides. PAS Staining Kit may also be used to aid in distinguishing a PAS positive secreting adenocarcinoma from an undifferentiated PAS negative squamous cell carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

Special Staining Kits for Connective Tissue

**Elastic Staining Kit**
Catalog Number: 860-005  
Ordering Code: 05279216001  
Quantity: 75 tests  
Controls: Kidney, Lung, Skin, Aorta, Artery

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**
Elastic Staining Kit is intended for use as a qualitative histologic stain to demonstrate elastic fibers in tissue sections in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

**Green for Trichrome**
Catalog Number: 860-032  
Ordering Code: 06521916001  
Quantity: 75 tests  
Controls: Colon, Kidney, Liver, Skin

For use on the BenchMark Special Stains system.

**INTENDED USE**
Green for Trichrome with Trichrome Staining Kit (860-031 / 06521908001) is intended for in vitro diagnostic (IVD) use. It is a qualitative histologic stain used to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

**Jones H&E Staining Kit**
Catalog Number: 860-019  
Ordering Code: 05279348001  
Quantity: 40 tests  
Controls: Kidney

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**
Jones Staining Kit is intended for use as a qualitative histologic stain to demonstrate capillary basement membrane in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.
**Jones Light Green Staining Kit**

Catalog Number: 860-020  
Ordering Code: 05279356001  
Quantity: 40 tests  
Controls: Kidney  

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Jones Light Green Staining Kit is intended for use as a qualitative histologic stain to demonstrate capillary basement membrane in tissue, such as kidney. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

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**Reticulum II Staining Kit**

Catalog Number: 860-024  
Ordering Code: 05279399001  
Quantity: 75 tests  
Controls: Tissue with Defined Reticular Fibers  
(Liver, Spleen, Kidney, or Lymph Nodes)

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Reticulum II Staining Kit is intended for use as a qualitative histologic stain to demonstrate reticular fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

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**Trichrome II Blue Staining Kit**

Catalog Number: 860-013  
Ordering Code: 05279283001  
Quantity: 75 tests  
Controls: Colon, Esophagus, Liver, Skin

For use on the NexES Special Stains system.

**INTENDED USE**

Ventana Medical Systems’ (Ventana) Trichrome II Staining Kit is intended for in vitro diagnostic (IVD) use as a qualitative histologic stain to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.
**Trichrome III Blue Staining Kit**

- **Catalog Number:** 860-022
- **Ordering Code:** 05279364001
- **Quantity:** 75 tests
- **Controls:** Colon, Esophagus, Liver, Skin

*For use on the NexES Special Stains system.*

**INTENDED USE**

Ventana Medical Systems’ (Ventana) Special Stains Trichrome III Blue Staining Kit is intended for in vitro diagnostic use (IVD) as a qualitative histologic stain to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

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**Trichrome III Green Staining Kit**

- **Catalog Number:** 860-023
- **Ordering Code:** 05279372001
- **Quantity:** 75 tests
- **Controls:** Colon, Esophagus, Liver, Skin

*For use on the NexES Special Stains system.*

**INTENDED USE**

Ventana Medical Systems’ (Ventana) Special Stains Trichrome III Green Staining Kit is intended for in vitro diagnostic use (IVD) as a qualitative histologic stain to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

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**Trichrome Staining Kit**

- **Catalog Number:** 860-031
- **Ordering Code:** 06521908001
- **Quantity:** 60 tests
- **Controls:** Colon, Kidney, Liver, Skin

*For use on the BenchMark Special Stains system.*

**INTENDED USE**

Trichrome Staining Kit is a qualitative histologic stain used to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.
Special Staining Kits for Microorganisms

**AFB III Staining Kit**

Catalog Number: 860-027  
Ordering Code: 05279437001  
Quantity: 75 tests  
Controls: Tissue Positive for Acid-Fast Bacteria

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

AFB III Staining Kit is intended for use as a qualitative histologic stain to selectively demonstrate *Mycobacterium* and other acid fast organisms or components in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

**Alcian Yellow Staining Kit**

Catalog Number: 860-017  
Ordering Code: 05279321001  
Quantity: 75 tests  
Controls: Tissue Positive for *H. pylori* (Stomach, Gastric Ulcer)

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Alcian Yellow Staining Kit is intended for in vitro diagnostic (IVD) use as a qualitative histologic stain for *H. pylori* in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

**GMS II Staining Kit**

Catalog Number: 860-028  
Ordering Code: 05412749001  
Quantity: 75 tests  
Controls: Tissue Positive for Pathogenic Fungus or *P. carinii*

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

GMS II Staining Kit is intended for use as a qualitative histologic stain to demonstrate polysaccharides in the cell walls of fungi and other opportunistic organisms in formalin-fixed, paraffin-embedded tissue. This stain is primarily used to distinguish pathogenic fungi such as *Aspergillus* and *Blastomyces* and other opportunistic organisms such as *P. carinii* in tissue sections. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

**Gram Staining Kit**

Catalog Number: 860-039  
Ordering Code: 06890105001  
Quantity: 75 tests  
Controls: See Package Insert

For use on the BenchMark Special Stains system.

**INTENDED USE**

Gram Staining Kit is intended for use as a qualitative histologic stain to demonstrate gram-negative and gram-positive bacteria in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

**Steiner Staining Kit**

Catalog Number: 860-018  
Ordering Code: 05279330001  
Quantity: 40 tests  
Controls: Tissue with *H. pylori* Organisms and Gastric Ulcer

For use on the NexES Special Stains system.

**INTENDED USE**

Ventana Medical Systems’ (Ventana) Special Stains Steiner Staining Kit is intended for in vitro diagnostic (IVD) use as a qualitative histologic silver stain to aide in the identification of the causative organisms of diseases such as syphilis, some gastric ulcers (*H. pylori*), Lyme disease, Legionnaire’s disease, cat scratch fever, and others in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

**Steiner II Staining Kit**

Catalog Number: 860-030  
Ordering Code: 06521894001  
Quantity: 40 tests  
Controls: Tissue Containing *H. pylori*, Spirochetes, or *L. pneumophila*

For use on the BenchMark Special Stains system.

**INTENDED USE**

Steiner II Staining Kit is intended for in vitro diagnostic (IVD) use. It is a qualitative histologic stain used to study specific argyrophilic microorganisms in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.
Other Special Staining Kits

Congo Red Staining Kit

**Catalog Number:** 860-026  
**Ordering Code:** 05279429001  
**Quantity:** 40 tests  
**Controls:** Tissue Positive for Amyloid

For use on the BenchMark Special Stains and NexES Special Stains systems.

**INTENDED USE**

Congo Red Staining Kit is intended for use as a qualitative histologic stain to selectively demonstrate amyloid in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

Giemsa Staining Kit

**Catalog Number:** 860-006  
**Ordering Code:** 05279224001  
**Quantity:** 75 tests  
**Controls:** Bone Marrow, Lymph Node, Spleen

**INTENDED USE**

Giemsa Staining Kit is intended for in vitro diagnostic (IVD) use as a qualitative histologic stain to differentiate leukocytes in bone marrow and other hematopoietic tissue (lymph nodes) in formalin-fixed, paraffin-embedded tissue. The stain can also be used to demonstrate some microorganisms, such as *H. pylori*. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

Iron Staining Kit

**Catalog Number:** 860-009  
**Ordering Code:** 05279259001  
**Quantity:** 75 tests  
**Controls:** Tissue with Intracellular or Extracellular Iron (Liver, Bone Marrow or Spleen)

**INTENDED USE**

Iron Staining Kit is intended for use as a qualitative histologic stain to detect iron pigment in bone marrow, tissue with hemochromatosis, and hemosiderosis in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.
SPECIAL STAINING KITS
Leadership

Knowledge and experience underscored by the world’s largest installed base of IHC/ISH automated staining instruments
The VENTANA HE 600 system fully automates H&E staining, from tissue drying through coverslipping. Featuring individual slide staining and Lean design for intuitive operation, the system provides enhanced quality, workflow and safety that benefits both patients and pathology professionals.

**Quality**
- **Count on accurate, reproducible stains:** Consistent, high-quality stains provide confidence in patient diagnosis.

**Workflow**
- **Improve laboratory workflow:** Lean workflow reduces touchpoints and wait points for improved lab efficiency and turnaround time.

**Safety**
- **Increase lab safety:** Elimination of xylene and alcohol increases safety for technicians and the environment.
- **Improve patient safety:** Individual slide staining mitigates cross-contamination, providing greater patient safety.

### VENTANA HE 600 system ancillary products

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<th>Product</th>
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<td>VENTANA HE 600 system Eosin</td>
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<td>VENTANA HE 600 system Differentiating Solution</td>
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<td>VENTANA HE 600 system Bluing</td>
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<td>VENTANA HE 600 system Organic Solution</td>
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<td>VENTANA HE 600 system Transfer Fluid</td>
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<tr>
<td>VENTANA HE 600 system Coverslips</td>
<td>06711138001</td>
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</table>
**Individual slide staining**

Fresh reagents on every slide produce consistent, high-quality H&E stains for excellent clarity and enhanced visualization of micro-anatomic detail. Discrete staining for every patient slide protects against tissue cross-contamination.

**Protocol flexibility**

The system supports more than 400 different protocols with customization options for optimizing stain intensity to meet pathologists’ preferences.

**Reagent management**

All reagents are ready to use, with no mixing or dilution needed, so laboratory staff can focus on more value-added activities. The reagents are recyclable, poke yoke designed, color coded and individually numbered with radio frequency identification (RFID) technology for easy management and error prevention.

**Remote monitoring and technical assistance**

The VENTANA HE 600 system is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

For ordering information, contact your Roche representative.

**Protecting the integrity of Sue’s slide**

H&E staining is the critical first step in making a cancer diagnosis based on biopsy. The VENTANA HE 600 system utilizes individual slide staining, which mitigates tissue specimen cross-contamination and helps safeguard patients from the risk of misdiagnosis. Improved quality in H&E staining enhances pathologists’ diagnostic confidence to help ensure the right diagnosis for Sue and patients like her.
BenchMark ULTRA system

True continuous access IHC/ISH slide staining

Offering unprecedented workflow efficiency, the VENTANA BenchMark ULTRA system enables your lab to process samples as they arrive and easily manage urgent requests. The fully integrated staining solution delivers medical value through continuous and random processing of patient samples.

- **Maximize capacity:** Individual slide drawers enable single piece flow to limit wasted slide positions.

- **Optimize efficiency:** Single piece workflow allows for protocol flexibility and continuous access to each slide without sacrificing stain quality.

- **Improve processing time:** Continuous flow decreases preparation time required for slide sorting and matching of reagent.

- **Quickly respond to test requests:** Ultimate Reagent Access (URA) allows immediate processing of urgent and late-arriving samples.

- **Increase workflow flexibility:** With 30 individual slide drawers and 35 reagent positions, the instrument enables you to add or remove slides and reagents at any time.

**Throughput flexibility**

IHC, ISH, SISH, Dual Stain and FITC slides can be processed simultaneously, improving turnaround times. The fully automated workflow enables processing of 90 slides in 8 hours, or 120 slides with an overnight run.

**Remote monitoring and technical assistance**

The BenchMark ULTRA system is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

**For ordering information, contact your Roche representative.**
BenchMark ULTRA bulk reagents

**EZ Prep (10x)**
Catalog Number: 950-102
Ordering Code: 05279771001
Quantity: 2 L bottle
Format: Concentrate

Ventana Medical Systems, Inc. (Ventana) EZ Prep Concentrate (10X) solution (EZ Prep) is used for paraffin removal from tissue samples during immunohistochemistry and in situ hybridization reactions, and to dilute 2X SSC during stringency washes during in situ hybridization reactions carried out on VENTANA automated slide stainers. This product is designed for use on BenchMark Series automated slide stainers. This reagent is intended for in vitro diagnostic (IVD) use.

**Reaction Buffer (10x)**
Catalog Number: 950-300
Ordering Code: 05353955001
Quantity: 2 L bottle
Format: Concentrate

Ventana Medical Systems, Inc. (Ventana) Reaction Buffer Concentrate (10X) is a Tris based buffer solution (pH 7.6 ± 0.2) used to rinse slides between staining steps and provide a stable aqueous environment for the immunohistochemistry (IHC) or in situ hybridization (ISH) reactions carried out on BenchMark and BenchMark XT automated slide staining systems. This reagent is intended for in vitro diagnostic (IVD) use.

**ULTRA Cell Conditioning (ULTRA CC1)**
Catalog Number: 950-224
Ordering Code: 05424569001
Quantity: 2 L bottle
Format: Ready to Use

ULTRA Cell Conditioning Solution (ULTRA CC1) from Ventana Medical Systems, Inc. (Ventana) is a pre diluted solution used as a pretreatment step in the processing of tissue samples for immunohistochemistry (IHC) reactions carried out on the VENTANA BenchMark ULTRA instrument. This product is intended for in vitro diagnostic (IVD) use.

**ULTRA Cell Conditioning (ULTRA CC2)**
Catalog Number: 950-223
Ordering Code: 05424542001
Quantity: 1 L bottle
Format: Ready to Use

Ventana Medical Systems, Inc. (Ventana) ULTRA Cell Conditioning Solution (ULTRA CC2) is a prediluted solution used as a pretreatment step in the processing of tissue samples during immunohistochemistry (IHC) and in situ hybridization (ISH) on the VENTANA BenchMark ULTRA instrument. This product is intended for in vitro diagnostic (IVD) use.

**ULTRA LCS (Predilute)**
Catalog Number: 650-210
Ordering Code: 05424534001
Quantity: 2 L bottle
Format: Ready to Use

ULTRA LCS (Predilute) from Ventana Medical Systems, Inc. (Ventana), also known as ULTRA LCS or ULTRA Liquid Coverslip (High Temperature), is a prediluted coverslip solution used as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the immunohistochemistry or in situ hybridization reactions carried out on the VENTANA BenchMark ULTRA instrument. This product is intended for use on the VENTANA BenchMark ULTRA instrument. This reagent is not to be used on the VENTANA NexES IHC, NexES Special Stains or ES Automated Slide Stainers. This reagent is intended for in vitro diagnostic use.

**SSC (10X)**
Catalog Number: 950-110
Ordering Code: 05353947001
Quantity: 2 L bottle
Format: Concentrate

Ventana Medical Systems, Inc. (Ventana) 10X SSC, Sodium Chloride Sodium Citrate buffer solution is used for stringency washes and to rinse slides between staining steps and provide a stable aqueous environment for the in situ hybridization reactions carried out on a VENTANA automated slide stainer. This reagent is intended for in vitro diagnostic use.
BenchMark XT system

Automated IHC/ISH slide staining

The VENTANA BenchMark XT system offers the flexibility to expand your test menu, increase testing volume and improve turnaround time. The fully automated, random-access platform delivers consistent, high-quality results while improving workflow and efficiency.

- **Enhance flexibility:** Users can simultaneously process IHC, ISH, SISH, Dual Stain and FITC slides in the same run without limitations on protocol compatibility.

- **Increase efficiency:** The fully automated workflow decreases preparation time required for slide sorting.

- **Improve turnaround time:** Full automation increases slide throughput by 25% and eliminates labor by 80% compared to manual and semiautomated staining.

**Throughput capabilities**

The BenchMark XT system features a single drawer with 30 slide positions, each with individual temperature control, and a reagent carousel with 35 positions. The fully automated workflow enables processing of up to 60 slides in 8 hours, or 90 slides with an overnight run.

**For ordering information, contact your Roche representative.**
**BenchMark XT bulk reagents**

**Cell Conditioning 1 (CC1)**
Catalog Number: 950-124
Ordering Code: 05279801001
Quantity: 2 L bottle
Format: Ready to Use

Ventana Medical Systems, Inc. (Ventana) Cell Conditioning Solution (CC1) is a pre diluted solution used as a pretreatment step in the processing of tissue samples for immunohistochemistry (IHC) reactions carried out on VENTANA BenchMark and BenchMark XT automated slide stainers. This reagent is intended for in vitro diagnostic use.

**Cell Conditioning 2 (CC2)**
Catalog Number: 950-123
Ordering Code: 05279798001
Quantity: 1 L bottle
Format: Ready to Use

Ventana Medical Systems, Inc. (Ventana) Cell Conditioning Solution (CC2) is a prediluted solution used as a pretreatment step in the processing of tissue samples during immunohistochemistry (IHC) and in situ hybridization (ISH) on VENTANA BenchMark, BenchMark GX, and BenchMark XT instruments. This product is intended for in vitro diagnostic (IVD) use.

**EZ Prep (10x)**
Catalog Number: 950-102
Ordering Code: 05279771001
Quantity: 2 L bottle
Format: Concentrate

Ventana Medical Systems, Inc. (Ventana) EZ Prep Concentrate (10X) solution (EZ Prep) is used for paraffin removal from tissue samples during immunohistochemistry and in situ hybridization reactions, and to dilute 2X SSC during stringency washes during in situ hybridization reactions carried out on VENTANA automated slide stainers. This product is designed for use on BenchMark Series automated slide stainers. This reagent is intended for in vitro diagnostic (IVD) use.

**LCS (predilute)**
Catalog Number: 650-010
Ordering Code: 05264839001
Quantity: 2 L bottle
Format: Ready to Use

Ventana Medical Systems, Inc. (Ventana) LCS (Predilute), also known as LCS or Liquid Coverslip (High Temperature) is a prediluted coverslip solution used as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the immunohistochemistry or in situ hybridization reactions carried out on VENTANA automated slide stainers. This product is designed for use on the BenchMark and BenchMark XT automated slide stainers. This reagent is not to be used on the VENTANA NexES IHC, NexES Special Stains or ES automated slide stainers. This reagent is intended for in vitro diagnostic use.

**Reaction Buffer (10x)**
Catalog Number: 950-300
Ordering Code: 05353955001
Quantity: 2 L bottle
Format: Concentrate

Ventana Medical Systems, Inc. (Ventana) Reaction Buffer Concentrate (10X) is a Tris based buffer solution (pH 7.6 ± 0.2) used to rinse slides between staining steps and provide a stable aqueous environment for the immunohistochemistry (IHC) or in situ hybridization (ISH) reactions carried out on BenchMark and BenchMark XT automated slide staining systems. This reagent is intended for in vitro diagnostic (IVD) use.

**SSC (10X)**
Catalog Number: 950-110
Ordering Code: 05353947001
Quantity: 2 L bottle
Format: Concentrate

Ventana Medical Systems, Inc. (Ventana) 10X SSC, Sodium Chloride Sodium Citrate buffer solution is used for stringency washes and to rinse slides between staining steps and provide a stable aqueous environment for the in situ hybridization reactions carried out on a VENTANA automated slide stainer. This reagent is intended for in vitro diagnostic use.
DISCOVERY ULTRA system
The flexibility of manual, the freedom of automation

Offering our highest level of protocol flexibility for assay development, the VENTANA DISCOVERY ULTRA system enables your lab to fully automate a wide variety of IHC and ISH assays with the freedom to shape the platform to your project requirements.

- **Save valuable development time**: Fully automated baking through staining and ready-to-use reagents minimize manual steps.

- **Improve workflow efficiency**: True random access enables addition and removal of reagents to support multiple assay types and users.

- **Achieve clear, sensitive detection**: Innovative reagents, five color options and enhanced immuno-fluorescence capabilities enable reproducible, high-quality IHC and ISH stains.

- **Accelerate assay development**: Open software, protocol flexibility and reagent choice streamline optimization of automated high-complexity assays.

**Throughput flexibility**

With 30 independent reaction chambers, the DISCOVERY ULTRA system enables you to run both manual and fully automated experiments simultaneously with no synchronization errors. The system provides the ability to fully automate a broad range of IHC and ISH assays, including FISH, gene and protein IHC/ISH, mRNA ISH and multiplex assays (with any combination of IHC and ISH).

*For ordering information, contact your Roche representative.*
DISCOVERY XT system

Efficiency and flexibility for IHC/ISH research

The VENTANA DISCOVERY XT system offers exceptional reproducibility and productivity for IHC and ISH slide preparation and processing for research. The flexible platform and sophisticated detection and reagent systems will help you accelerate the discovery of new targets and biomarkers.

- **Increase efficiency**: Fully automated baking through staining and ready-to-use reagents reduce manual steps for enhanced productivity.

- **Improve workflow flexibility**: Assay automation with your choice of reagents and detection chemistry gives you flexibility to meet your project needs.

- **Rely on consistent quality**: Ready-to-use reagents optimized for automation enhance slide-to-slide and run-to-run reproducibility.

**Throughput capabilities**

The DISCOVERY XT system enables fully automated processing of IHC, ISH and FISH assays—individually or simultaneously. The instrument provides individual temperature control for precise heating of up to 30 slides and has a capacity of up to 35 reagents.

**DISCOVERY products are for research use only.**

Not for use in diagnostic procedures.

For ordering information, contact your Roche representative.

**Giving Robert hope for a breakthrough**

The same innovation that goes into our VENTANA BenchMark IHC/ISH staining systems for clinical use is found in the VENTANA DISCOVERY line of research-use-only instruments. The high-quality data generated on DISCOVERY IHC/ISH research instruments help your lab uncover information that can lead to better understanding of disease and, in turn, enable advances in treatment. Your next discovery could be the one that helps patients like Robert have a brighter future.
BenchMark Special Stains system
Automated baking through staining

Building on the industry-leading BenchMark system technology, the VENTANA BenchMark Special Stains instrument brings complete baking through staining to the histology laboratory for special stains, so your lab can consistently deliver exceptional quality.

Quality
• Deliver reliable, high-quality stains: Ready-to-use, quality-controlled reagents provide consistent staining quality.

Safety
• Improve lab safety: Reduced exposure to harmful chemicals decreases risk to technicians.
• Safeguard patients: Individual slide staining helps protect patient samples.

Workflow
• Achieve superior workflow efficiency: Manual processes and temperature dependencies are eliminated through automated deparaffinization and independent slide heating.
• Expand your lab’s capabilities: Reducing manual processes frees laboratory professionals for high-value activities.
• Improve efficiencies: Automated baking through staining, random batch access, and bulk and waste fluid sensing improve turnaround time and optimize workflow.
• Expand capacity: The BenchMark Special Stains system features 20 slide positions, each with independent temperature control, and a reagent carousel with 25 positions.

• Simplify operation: The intuitive VENTANA System Software interface, used with all BenchMark systems, simplifies operation and enables connection to a BenchMark ULTRA instrument.

Remote monitoring and technical assistance
The BenchMark Special Stains automated slide stainer is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

For ordering information, contact your Roche representative.
Special Stains Wash Two Part Kit
Catalog Number: 860-040
Ordering Code: 07383568001
Quantity: 1 Kit
Ventana Medical Systems, Inc.'s (Ventana) Special Stains Wash Two Part Kit is used on the VENTANA BenchMark Special Stains automated slide stainer and VENTANA NexES Special Stains automated slide stainer. When diluted according to instructions, Special Stains Wash Two Part Kit produces an optimized solution for use with the VENTANA special stains reagent kits. This solution provides a stable aqueous environment for special histological staining reactions.

BenchMark Special Stains Deparaffinization Solution (10X)
Catalog Number: 860-036
Ordering Code: 06523102001
Quantity: 2 L bottle
Format: Concentrate
BenchMark Special Stains Deparaffinization Solution (10X) is used for paraffin removal from tissue samples during special stains reactions carried out on the VENTANA BenchMark Special Stains automated slide stainer. This reagent is intended for in vitro diagnostic (IVD) use.

BenchMark Special Stains Wash Solution (10X)
Catalog Number: 860-035
Ordering Code: 06523099001
Quantity: 2 L bottle
Format: Concentrate
BenchMark Special Stains Wash Solution (10X) is used on the VENTANA BenchMark Special Stains automated slide stainer. When diluted according to instructions, BenchMark Special Stains Wash Solution (10X) is an optimized solution used for VENTANA special stains reagent kits used on the VENTANA BenchMark Special Stains automated slide stainer. This solution provides a stable aqueous environment for special histological staining reactions performed on the VENTANA BenchMark Special Stains automated slide stainer. This product is intended for in vitro diagnostic (IVD) use.

Special Stains Cleaning Kit
Catalog Number: 860-016
Ordering Code: 05279313001
Quantity: 50 cleaning cycles
VENTANA Special Stains Cleaning Kit is intended for use during the automated cleaning procedure on the VENTANA BenchMark Special Stains automated slide stainer and the VENTANA NexES Special Stains automated slide stainer. This kit is intended for in vitro diagnostic use.

Special Stains Clean Plus
Catalog Number: 860-037
Ordering Code: 06649327001
Quantity: 50 cleaning cycles
The Special Stains Clean Plus, used with the Special Stains Cleaning Kit (860-016), is used to provide a deep clean of the reagent aspiration and dispense mechanism of the BenchMark Special Stains system. *1 kit for 50 cleaning cycles. (Standard cleaning cycle)
VENTANA Digital Pathology Solutions
Transforming the practice of pathology
to improve patient care

Our growing family of VENTANA innovations is changing the practice of pathology, empowering you with a comprehensive image and workflow solution that helps inform decision making, deliver medical value and improve patient outcomes.

- **Increase workflow efficiency**: When used together, our integrated staining platforms, assays, scanners, algorithms and workflow management solution optimize your process, from staining to reporting.

- **Deliver enhanced medical value**: Anywhere, anytime access and algorithm-based image analysis support efficient and informed treatment decisions.

- **Improve patient care**: Sharing digital images in real time, with instant access to expertise, eliminates the boundaries of time and distance for faster treatment decisions.

---

**Bringing confidence to Sam’s diagnosis**

VENTANA digital pathology solutions are changing the practice of medicine to benefit patients like Sam. Digital images of a patient’s tissue slide can be shared for remote consults and quick access to second opinions. Tissue specimens undergo precise assay scoring and image analysis for consistent, objective interpretations. VENTANA digital pathology solutions offer Sam and patients like him peace of mind by enabling pathologists to share images and expertise to help improve diagnostic and treatment decisions.
Virtuoso Image and Workflow Management Software

*Built for the clinical laboratory*

**VENTANA Virtuoso software** combines rich functionality with an easy-to-use interface to deliver a complete digital pathology solution, from image management to customized reporting.

- **Enhance patient care:** Timely, efficient access to slide images enables real-time collaboration, with faster turnaround for second opinions.

- **Improve patient safety:** Integration with VENTANA VANTAGE software provides efficient data entry and specimen tracking.

- **Increase flexibility:** Distributed pathology workflow enables remote viewing and case sharing, while role-based portals enhance ease of use.

- **Expand your reach:** Web-based software application simplifies access and makes it easy to add new users.

View, annotate and analyze slide images anytime, anywhere.
Companion Algorithm Image Analysis Software
Clinical confidence with a comprehensive breast cancer diagnostic panel

VENTANA Companion Algorithm image analysis software is integrated with VENTANA Virtuoso image and workflow management software, VENTANA BenchMark IHC/ISH staining instruments and the VENTANA iScan Coreo slide scanner to provide optimized processing, from staining to reporting.

- **Improve clinical confidence**: Using the algorithms enables a pathologist to make consistent, objective interpretations, thus reducing both intra- and inter-observer variability in interpretation.

- **Ease reimbursement processes**: Using our algorithms can alleviate the burden of undergoing a payer-specific technical review, if required.

The most advanced, clinically validated pathology solutions

Roche was the first company in the industry to offer a comprehensive breast portfolio. Our full breast panel includes HER2 (4B5), ER (SP1), PR (1E2), Ki-67 (30-9) and p53 (DO-7) image analysis algorithms for use along with their accompanying VENTANA IHC assays.*

All IHC breast markers in the VENTANA portfolio have both image analysis and digital read applications available for use with the iScan Coreo slide scanner. There are two intended uses:

- Clinical use of the software algorithm to semi-quantify the biomarker

- Digital read to manually read and score the biomarker using a computer monitor

*Algorithms are for use only on the iScan Coreo scanner.
Roche offers VENTANA image analysis companion algorithms for the five key breast panel biomarkers

The VENTANA Companion Algorithm Estrogen Receptor (ER) (SP1) image analysis software

The VENTANA Companion Algorithm HER2 (4B5) image analysis software

The VENTANA Companion Algorithm Ki-67 (30-9) image analysis software

The VENTANA Companion Algorithm p53 (DO-7) image analysis software

The VENTANA Companion Algorithm Progesterone Receptor (PR) (1E2) image analysis software

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The VENTANA iScan Coreo slide scanner is the right fit for small- to medium-volume laboratories, offering 160-slide capacity with a small footprint for placement flexibility. Paired with VENTANA Virtuoso software, it provides a complete digital pathology solution, from image acquisition through customized reporting.

- **Increase confidence in results**: The instrument has FDA clearance for both digital read and image analysis on the five key breast panel markers: ER, PR, HER2, Ki-67 and p53.

- **Enhance flexibility**: Scanning at four objectives (4x, 10x, 20x and 40x) and the unique web-based Live Mode application for remote viewing and collaboration, provide versatility.

- **Improve efficiency**: Walkaway scanning, digital image archiving and customized reporting increase operational efficiencies and productivity.

**Remote monitoring and technical assistance**

The iScan Coreo slide scanner is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

**For ordering information, contact your Roche representative.**

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**iScan Coreo slide scanner. Pathology. Advanced.**

- High-speed brightfield scanning—a 15 x 15 mm tissue area can be scanned in less than two minutes at 20x
- Automatic slide detection for walkaway scanning, with random access to the slide rack
- Automatic tissue region identification with option to manually override
- Volume scanning with the ability to capture multiple z-plane images
- Integrated with image viewing software that supports annotation and precise digital measurements

**iScan Image Viewer software**

- Windows application used to view local and remote iScan images instantly
- Precise digital tools for annotation, measurement and cell counting
- Simultaneous multiple image viewing
- Images can be viewed at magnifications ranging from 1x to 80x (80x achieved with digital zoom)
- Export areas of interest
The industry’s most powerful brightfield scanner, the VENTANA iScan HT slide scanner is built for high-volume laboratories. With a throughput of ~80 slides per hour at 20x and an intuitive user interface, the scanner design is targeted towards speed, efficiency and flexible workflow.

**• Improve efficiency:** High-speed, high-throughput scanning with a 360-slide capacity increases productivity.

**• Optimize workflow:** Continuous random access and STAT slide override allows users to prioritize and change workflow at a moment’s notice.

**• Enhance flexibility:** Users can customize profiles of frequently seen cases, utilize 1D and 2D barcode reading and choose 20x or 40x magnification.

**Remote monitoring and technical assistance**

The VENTANA iScan HT slide scanner is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

**For ordering information, contact your Roche representative.**
VENTANA Vector Software
Software for education and collaboration

VENTANA Vector software is Research Use Only (RUO) software for academic medical centers and pathology groups who wish to share digital slides with students or other pathologists for education and collaboration.

- **Enhance the learning experience:** Unlike the microscope, the software enables standardization of content (including rare cases) and provides flexible content and evaluation management tools, based on teaching or project objectives.

- **Increase engagement:** Images can be viewed by multiple participants at any time, and users can create quizzes for students and forums to foster group collaboration.

- **Optimize efficiency:** Anywhere, anytime access creates a collaborative learning environment for students as well as pathologists who are working remotely on projects.

VENTANA Vector software is for research use only. Not for use in diagnostic procedures. Access using tablets, mobile phones and desktop computers.
The **VENTANA VANTAGE workflow solution** helps protect patients from the serious risks associated with sample misidentification. Finally, labs can enjoy complete chain of custody, Lean integrated processes, and full visibility into lab operations any time, from anywhere.

- **Fully track lab operations**: Our comprehensive solution for histology labs—hardware, software and workflow consulting—offers a commanding view of your complex operation from a single strategic perspective.

- **Improve patient safety**: Implemented in over 200 labs worldwide, the VANTAGE workflow solution maintains positive sample ID with barcode scanners at each workstation and single piece flow workflow.

- **Increase efficiency**: The VANTAGE workflow solution is designed using Lean Six Sigma principles and includes expert workflow consulting to help you obtain immediate and ongoing workflow benefits.

- **Optimize workflow**: Immediately locate any patient’s slide, at any time, from any last scanned location. See a comprehensive dashboard of lab performance at any time.

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### VANTAGE workflow solution

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**Ensuring the identity of David’s specimen**

As the single, safety-focused point of connection in the anatomic pathology lab, VANTAGE workflow solution helps improve patient safety by ensuring complete chain of custody throughout the histology workflow. From sample accessioning to results, VANTAGE barcode-driven workflow management reduces errors and protects patients from the serious risks associated with sample misidentification. So David, and the medical team that cares for him, can be assured that high-confidence results are used to determine his diagnosis and treatment.
VENTANA Connect middleware solution provides an efficient point of connection from Laboratory Information Systems (LIS) to VENTANA systems and software, automatically exchanging critical case information and eliminating test request re-entries that can introduce errors and slow you down.

- **Optimize lab efficiency**: Single, flexible interface connects multiple LIS platforms to current and future VENTANA instruments.

- **Reduce errors**: Important case information flows seamlessly to instruments and systems through a single, secure connection.

- **Improve patient safety**: VENTANA instruments and software accept LIS-originated case identifiers, increasing patient safety by using a single unique identifier at every point in the process.
Ventana Workflow Consulting Solutions

Expert support to optimize workflow

Highly trained in Lean Six Sigma principles, our workflow consultants will work with you to help make your lab processes easier, faster, safer and more reliable. Working closely with your team, we’ll identify and address opportunities to optimize your workflow, maximize results and lower your costs.

- **Optimize workflow:** Standardized processes improve performance, throughput and turnaround times.

- **Improve patient safety:** Improved patient sample identification helps reduce errors and decrease risk.

- **Increase efficiency:** Simplifying workflow and eliminating non-value-added activities reduce costs and improve productivity.

- **Enhance patient care:** Streamlined processes help you deliver results faster, for earlier treatment decisions.

Optimize your lab’s performance from the moment you receive a sample to the time you deliver a patient’s results.
To help your lab achieve the greatest benefit from our products, Roche Commercial Education is committed to providing an engaging training experience with a range of resources focused on continuous learning and enhancing overall job proficiency.

Designed to prepare your lab for success, Roche Diagnostics University (RDU) is a one-stop online registration and learning platform supporting the right training, for the right role, at the right time.

- **Experience interactive learning:** Courses consist of an optimal mix of on-demand product and disease state e-Learning content, and Indianapolis-based classroom, hands-on experience.

- **Learn from experts:** Training is conducted by highly qualified histology instructors with professional certification, field or technical support expertise.

- **Gain proficiency:** Spanning the histology workflow process, RDU courses are designed to help you gain expertise with Roche instrumentation, including daily operation, maintenance and troubleshooting, through interactive participation.

- **Easily access training documentation:** Administrative dashboards provide easy access to training documentation, training history and program reports.

### Getting started

Ask your Roche representative for instructions on creating a Roche Diagnostics University account and for additional training details.
Roche Support Network (RSN)
Always on, always ready to help

At Roche, support is not an afterthought—it’s our promise and our passion. Backed by a variety of highly experienced, specialized teams, the Roche Support Network provides a host of solutions to assist you at every stage—from procurement to ongoing onsite and offsite support.

- **Get personalized support:** We work with you to build a foundation for success, assessing your needs and objectives to provide customized solutions based on your lab’s data and workflow, onsite observations and Lean Six Sigma techniques.

- **Gain peace of mind:** You can be confident knowing you’ll receive expert support, including project management and product training, to ensure peak performance and successful implementation with minimal disruption of lab operations.

- **Maintain optimal lab performance:** To ensure your success, we partner with you and provide ongoing support that includes remote monitoring, field service and technical applications expertise, consulting and a 24/7/365 call center.
CareGiver Remote Support

The help you need, when you need it

Because we understand the critical nature of the work you do for patients, Roche offers CareGiver remote support—an innovative automated support solution for anatomic pathology labs. Through a secure Internet connection, the CareGiver system provides continuous monitoring and remote service of VENTANA instruments,* helping maximize performance to keep your lab running smoothly.

- **Gain peace of mind:** Remote instrument monitoring, troubleshooting and training with secure data communication help keep your lab operating at peak performance.

- **Save time:** System software upgrades are provided via secure Internet connection, and improved, automated data collection decreases management time requirements.

- **Increase up time:** Remote monitoring and support help to maintain optimum instrument performance and reduce downtime.

*CareGiver remote support is currently available for the VENTANA HE 600 system, VENTANA BenchMark ULTRA IHC/ISH system, VENTANA BenchMark Special Stains platform, VENTANA Virtuoso software, VENTANA iScan Coreo slide scanner, and the VENTANA iScan HT slide scanner.
Reimbursement

Tough questions. One easy answer.

Reimbursement for the assays and services you provide can seem confusing. The Roche Diagnostics reimbursement team can help. Our team is a reliable and credible resource you can turn to for the latest information to address reimbursement questions and issues regarding Roche Diagnostics products.

- **Get the answers you need:** The Roche Diagnostics reimbursement team can help you address reimbursement questions about FDA-cleared or approved products marketed and sold in the U.S. by Roche Diagnostics Corporation and its affiliates.

- **Save time:** Our team monitors reimbursement trends and policies to keep track of the latest developments that might affect your business or have an impact on Roche Diagnostics products, so you can turn to us for answers and free up your time for more important activities.

- **Count on 24/7 support:** We’re available by phone or email around the clock, enabling you to contact our team for assistance at your convenience.

Reimbursement is complex.
Contacting us is easy.

If you are a healthcare professional working in a hospital, laboratory, physician office or other professional setting, you can contact our team for assistance at your convenience 24 hours a day, 7 days a week.

Please provide your name, the name of your organization and your contact information, and a brief description of your inquiry, via one of the following:

**Reimbursement Inquiry Line**
(toll-free voicemail and automated response system)
1–800–428–5074, ext. 13967

**Reimbursement Inquiry Email**
diagnostics.reimbursement@roche.com
Courage

Challenging the standard of care to improve the quality of patients’ lives
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