Roche receives FDA clearance for the cobas® Cdiff Test to detect Clostridium difficile

New test expands menu for healthcare associated infections testing on the widely adopted cobas®4800 System

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has provided 510(k) clearance for the cobas® Cdiff Test to detect Clostridium difficile (C. difficile) in stool specimens. The cobas® Cdiff Test targets the toxin B gene found in toxigenic C. difficile strains directly in specimens from symptomatic patients. The test provides accurate information which assists clinicians in making timely treatment decisions and aids in the prevention of further infection in healthcare settings.

"Having the ability to provide a result quickly is important when supporting infection control for Clostridium difficile," said Dr. Steve Young, Professor of Pathology, Department of Pathology UNMHSC and Tricore Reference Lab. "The cobas®4800 System has the capability to allow for mixed batch testing of the cobas®Cdiff Test alongside testing for Methicillin-resistant Staphylococcus aureus, Staphylococcus aureus, and herpes simplex virus 1 and 2*, all on one platform. We can run these assays together at least once in each shift rather than once a day, which can greatly improve laboratory efficiency, ultimately leading to better infection control and patient care."

In a clinical trial program conducted at sites throughout the United States, the cobas® Cdiff Test demonstrated excellent performance compared to direct and enrichment toxigenic culture. The test combines high assay sensitivity with rapid turnaround time and a minimum number of pre-analytic steps, to facilitate earlier intervention of patients suffering from C. difficile-associated disease. Earlier intervention can also lead to more effective implementation of infection control measures, which can prevent further transmission to additional patients.
“With the addition of the cobas® Cdiff Test to the cobas®4800 System menu, Roche is able to expand the tools available to assist clinicians in the management of healthcare associated infections,” said Paul Brown, head of Roche Molecular Diagnostics. “The cobas® Cdiff Test requires less sample handling and provides laboratories with a simplified workflow, when compared to other molecular methods. It also delivers a lower inhibition rate, which means fewer repeat samples and chances for error, enabling better patient care.”

About C. difficile
C. difficile is an anaerobic, toxin producing microorganism known to cause severe diarrhea, pseudomembranous colitis or toxic megacolon, in patients where normal bacterial flora of the gut has been altered following antibiotic therapy. Traditional methods for identification include toxigenic culture, which is labor intensive and slow, and enzyme immunoassays (EIA), which have limited sensitivity. Algorithms have been developed using combinations of culture and EIA testing for C. difficile toxins and/or a C. difficile-specific enzyme, glutamate dehydrogenase antigen (GDH), to improve the sensitivity of individual assays alone. Nucleic acid amplification tests provide sensitive and timely identification of patients with C. difficile infection, and exhibit better performance than EIAs.

About the cobas®4800 System
The cobas®4800 System offers true walk-away automation of nucleic acid purification, PCR set-up and real-time PCR amplification and detection to help laboratories achieve maximum efficiency. The expanding system menu in the U.S. currently includes the cobas®MRSA/SA Test, cobas®CT/NG Test (Chlamydia trachomatis/Neisseria gonorrhoeae), cobas®HPV Test, cobas®BRAF V600 Mutation Test, cobas®EGFR Mutation Test and cobas® KRAS Mutation Test.

About Roche
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and
chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit roche.com.

* Herpes simplex virus testing is not yet available for use in the US on the cobas®4800 System. A 510(k) submission is pending clearance.

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References:


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