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**FDA clears Roche high-volume immunoassay lab testing solution to support critical medical treatment decisions**

*cobas® e 801 module delivers on the promise of next-generation laboratory efficiency*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its new, dedicated high-volume testing immunoassay solution for the **cobas** 8000 modular analyzer series, the **cobas e 801** module, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA).

As core laboratories continue to evolve to meet the growing workload demands in an increasingly challenging environment, the **cobas e 801** module offers greater testing efficiency, superior reagent management and industry-leading turnaround time for critical diagnostic tests. Designed for maximum consolidation at a high throughput, the module reduces generated waste, for more environmentally sustainable testing.

“The **cobas e 801** module truly is a transformative solution,” said Dr. Alan Wright, Chief Medical Officer, Roche Diagnostics Corporation. “Patients and the physicians who serve them need medically relevant answers, faster and with ever greater precision. This clearance delivers the instrumentation cornerstone of the next-generation lab—high throughput, agility and intelligence.”

The **cobas e 801** module almost doubles the currently available immunoassay testing capacity on the same footprint, delivering up to 300 tests per hour and providing 48 reagent channels.

Designed to use at least 25% less patient sample than its predecessor, the analyzer offers an extensive assay menu and delivers speed, accuracy and consistency.

### *Advances that speed patient care*

The **cobas e 801** module is the newest member of the **cobas** 8000 modular analyzer series, delivering immunoassay testing across a wide range of disease areas. Up to four **cobas e 801** modules can be configured in a series, delivering up to 1,200 tests per hour across up to 192 reagent positions. The system may also be integrated with the **cobas** 8100 automated workflow series and Roche Middleware featuring Lab Intelligence.

The **cobas e 801** module allows for continuous, on-the-fly loading of reagents and consumables and has a high uptime, while requiring less hands-on time. A new reagent

pack design has increased reagent onboard stability to 16 weeks, allowing labs to reduce send-out testing and minimize reagent waste.

The **cobas e 801** module will continue to deliver Roche's industry-leading 9-minute STAT assays, allowing labs to reduce turnaround time for critical testing, such as cardiac markers. The small sample volumes required for testing are beneficial for patients, especially special populations like pediatrics and the critically ill.

### ***About Roche***

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalized healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims for improving patient access to medical innovations by working with all relevant stakeholders. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 billion. 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 [www.roche.com](http://www.roche.com).

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