Media Release

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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[1]. 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[2].

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.

References:

1. Cohen SH, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Infect Control Hosp Epidemiol 2010; 31:431–55.
2. Carroll KC. Tests for the diagnosis of Clostridium difficile infection: the next generation Anaerobe. 2011 Aug;17(4):170-4.

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