ICU
MANAGEMENT & PRACTICE

Roche Receives FDA Clearance for the Cobas Cdiff Test to Detect Clostridium Difficile

Roche (SIX: RO, ROG; OTCQX: RHHBY) has announced 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."

* 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.

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.”

Published on : Thu, 4 Jun 2015