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Roche receives FDA clearance for its Procalcitonin (PCT) assay to help clinicians effectively assess sepsis risk and manage sepsis patients

First IVD company to provide a fully integrated solution for PCT testing with Elecsys BRAHMS PCT

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced that it has received 510(k) clearance for its Elecsys BRAHMS PCT (procalcitonin) assay as a dedicated testing solution for people with severe sepsis or septic shock. With this clearance, Roche is the first IVD company in the U.S to provide a fully integrated solution for sepsis risk assessment and management.

PCT is a sepsis-specific biomarker associated with bacterial infection and PCT levels in blood can aid clinicians in assessing the risk of sepsis as well as managing the disease when present. The Elecsys BRAHMS PCT assay can aid in assessing the risk of critically ill patients to progress from severe sepsis to septic shock; and help determine the 28 day mortality risk in sepsis patients.

“Given the prevalence of sepsis in the U.S. – more than 1.6 million annual hospitalizations – this clearance is an important advancement in its assessment and management,” said Dr. Alan Wright, chief medical officer, Roche Diagnostics North America. “With such compelling clinical utilities and the automation advantages associated with Roche lab instrumentation, the Elecsys BRAHMS PCT test can provide healthcare professionals the confidence they need to manage this deadly disease.”

The clearance of Roche’s PCT solution is a result of the U.S. multicenter Procalcitonin Monitoring Sepsis Study (MOSES). The novel trial design of Thermo Fisher Scientific’s MOSES study leveraged the same patient samples to enable a “universal analysis” approach to demonstrate substantial equivalence to the FDA resulting in the clearance of the Elecsys BRAHMS PCT assay.

About Sepsis

Sepsis contributes to more than 1.6 million hospitalizations annually in the U.S., and is the most common cause of death in the ICU (Intensive Care Unit). Sepsis is a potentially life-threatening complication that can arise when the body develops a severe, over pronounced

inflammatory response to an infection. If unchecked, sepsis can rapidly progress leading to organ dysfunction and if not managed properly, may lead to death of the patient. Clinical manifestations of sepsis can be vague and may progress undetected by signs and symptoms to a severe condition.

While any individual with a severe infection has the potential to develop sepsis, the very young, the elderly and the immunocompromised are particularly vulnerable. Early diagnosis and management of sepsis, usually with antibiotics and large amounts of intravenous fluids, improves chances for survival.

About the performance of the Elecsys BRAHMS PCT PCT assay

The Elecsys BRAHMS PCT assay is designed to provide full automation, which means no reagent preparation or hands-on testing is required. This fast, reliable assay offers same-day testing capability with a short incubation time of only 18 minutes. It also has a broad measuring range (0.02 – 100 ng/mL, extending to 400 ng/mL with a recommended 1:4 dilution).

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. 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. 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.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. 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 seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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.

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