



PRESS RELEASE

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**B-R-A-H-M-S AKTIENGESELLSCHAFT RECEIVES FDA CLEARANCE TO MARKET
AUTOMATED PROCALCITONIN (PCT) TEST**

More Sensitive Blood Test Helps Improve Management of Infections

Hennigsdorf, Germany – B-R-A-H-M-S Aktiengesellschaft, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its patented Procalcitonin (PCT) Kryptor test system. The automated blood test will be used in critically ill patients as an aid to assess their risk for progression to severe sepsis and septic shock.

The B-R-A-H-M-S PCT sensitive Kryptor test will enable physicians to determine whether an infection is bacterial or viral in nature and provide actionable information on the severity of a patient's condition less than an hour after a blood sample is drawn. As the progression of severe bacterial infections is affected by how early the patient receives appropriate treatment, measuring PCT levels is valuable in hospitals where sepsis represents a major health challenge.

"PCT can improve critical decisions physicians have to make every day, including whether or not to administer antibiotics, thus avoiding unnecessary use of these powerful drugs and potentially reducing the length of stay in the ICU. Further studies will validate new standardized clinical decision rules that include the PCT test," said Dr. Eric H. Gluck, M.D., Director, Critical Care Services, Swedish Covenant Hospital in Chicago.

Adding PCT to the treatment paradigm will increase the ability to quickly assess a patient's condition, make timely treatment decisions and reduce further complications. "Procalcitonin is used in numerous hospitals worldwide since several years," said B-R-A-H-M-S CEO, Bernd Wegener. "The FDA decision will enable us to extend our strong international growth to hospitals in the US. This is an important milestone for B-R-A-H-M-S, and we look forward to introducing additional innovative tests to the U.S. that will improve patient care."

Numerous studies have proven the significance of a PCT test in the early recognition of bacterial infection and sepsis. PCT levels are undetectable in healthy individuals. However PCT levels rise rapidly when there is the presence of a bacterial infection. The quick results provided by the Kryptor will aid health care professionals to rapidly identify patients with serious bacterial infection.

About Sepsis

Sepsis is a complex clinical syndrome that is defined as the systemic inflammatory response of the body to an infection. It is the most common underlying cause of death in non-coronary ICUs where the mortality rate can be as high as 32 percent or 54 percent in cases of severe sepsis or septic shock, respectively. Every year, severe sepsis (i.e. sepsis complicated by organ dysfunction) strikes an estimated 751,000 people in the U.S. alone with a total cost to the healthcare system of \$16.7 billion (USD). Mainly as a result of the aging of the population, the incidence of severe sepsis in the U.S. is expected to rise to close to one million by the end of the decade. Early recognition of sepsis and timely initiation of appropriate therapy is key for survival from this potentially devastating condition.

About Procalcitonin (PCT)

In healthy people, PCT is produced in thyroid cells as a precursor for the hormone calcitonin and cannot be found in human blood. However, bacterial infections cause PCT to be produced by almost every organ of the body, resulting in a rapid rise of PCT levels in the blood. Viral infections do not cause this increase in PCT blood levels. The level of PCT in the blood is a reflection of the severity of bacterial infection, ranging from slightly elevated concentrations in infections with minor systemic inflammatory response to very high values in cases of severe sepsis and septic shock. Once an infection is under control, Procalcitonin levels decrease rapidly. This makes PCT an effective tool aiding physicians in the diagnosis of bacterial infection and sepsis. For additional information on Procalcitonin, please visit www.procalcitonin.com.

About B·R·A·H·M·S Aktiengesellschaft

B·R·A·H·M·S develops and distributes innovative biomarker tests worldwide through own sales organizations, distributors and licensees. These products improve patient management of medically critical and economically relevant diseases. Based on its own extensive proteomic research program, B·R·A·H·M·S continuously identifies innovative biomarkers which extend the company's large patent-protected portfolio. Besides PCT, new test panels for cardiac and infectious diseases are currently evaluated in large international clinical trial projects. B·R·A·H·M·S Aktiengesellschaft has its headquarters in Hennigsdorf near Berlin, Germany. For more information, go to www.brahms.de and www.procalcitonin.com

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