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Indications for Use

The B•R•A•H•M•S PCT sensitive KRYPTOR® is an immunofluorescent assay using Time-Resolved Amplified Cryptate Emission (TRACE®) technology to determine the concentration of PCT (procalcitonin) in human serum and EDTA or heparin plasma.

The B•R•A•H•M•S PCT sensitive KRYPTOR® is intended to be performed on B•R•A•H•M•S KRYPTOR® analyzer family.

The B•R•A•H•M•S PCT sensitive KRYPTOR® is intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.

The B•R•A•H•M•S PCT sensitive KRYPTOR® is also intended for use to determine the change in PCT level over time as an aid in assessing the cumulative 28-day risk of all-cause mortality in conjunction with other laboratory findings and clinical assessments for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission.

Procalcitonin (PCT) is a biomarker associated with the inflammatory response to bacterial infection that aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock. The percent change in PCT level over time also aids in the prediction of cumulative 28-day mortality in patients with severe sepsis and septic shock.

PCT levels on the first day of ICU admission above 2.0 µg/L are associated with a higher risk for progression to severe sepsis and/or septic shock than PCT levels below 0.5 µg/L.
A PCT level that declines ≤ 80% from the day that severe sepsis or septic shock was clinically diagnosed (Day 0) to four days after clinical diagnosis (Day 4) is associated with higher cumulative 28-day risk of all-cause mortality than a decline > 80%.

The combination of the first PCT level (≤ 2.0 µg/L or > 2.0 µg/L) at initial diagnosis of severe sepsis or septic shock with the patient's clinical course and the change in PCT level over time until Day 4 provides important additional information about the mortality risk.

The PCT level on Day 1 (the day after severe sepsis or septic shock is first clinically diagnosed) can be used to calculate the percent change in PCT level at Day 4 if the Day 0 measurement is unavailable.

Warnings and Precautions

B•R•A•H•M•S PCT sensitive KRYPTOR® is not indicated to be used as a stand-alone diagnostic assay to determine the risk of 28 day all-cause mortality. Changes in PCT should always be interpreted in the context of the clinical status of the patient and other laboratory results. There is no uniformly recognized interpretation of the change in PCT concentration levels for the prediction of mortality, and overall mortality is strongly dependent on many factors, including pre-existing patient risk factors and clinical course. The need to continue ICU care at Day 4 and other covariates (e.g., age, SOFA score) are also significant predictors of 28-day cumulative mortality risk. Validation of the B•R•A•H•M•S PCT sensitive KRYPTOR® as an aid in predicting mortality was performed in a study population with an overall 28-day mortality of 22%.

Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.