

ARCHITECT B·R·A·H·M·S PCT (PROCALCITONIN)

BACKGROUND

Sepsis is an issue for healthcare systems.

- >1.6 million people are diagnosed with sepsis in the U.S. each year (1 every 20 seconds)¹
- Sepsis is the #1 cost of hospitalization in the U.S. (over \$24 billion each year)¹
- Sepsis Progression to Clostridium Difficile can impact hospital reimbursement through CMS penalties of hospital acquired conditions²
- Mortality from sepsis increases 8% every hour that treatment is delayed¹

Procalcitonin aids in the diagnosis and patient management of sepsis.

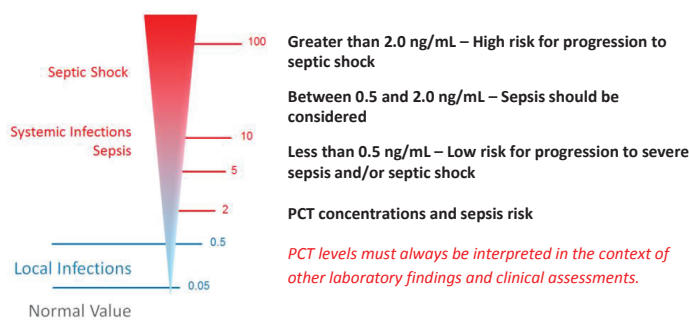
- Procalcitonin (PCT) helps determine if the patient has a bacterial infection (sepsis), the severity of the infection and is the patient responding to therapy³
- PCT is a more accurate diagnostic parameter for sepsis, a better predictor of mortality and a more reliable marker than other biomarkers including C-reactive protein, Interleukins and Lactate levels⁴
- A study of a healthcare system found that by implementing a sepsis protocol utilizing the clinical utility of PCT, they were able to reduce their Clostridium Difficile (C Diff) infections by 54%⁵

VALUE TO YOUR LAB⁶

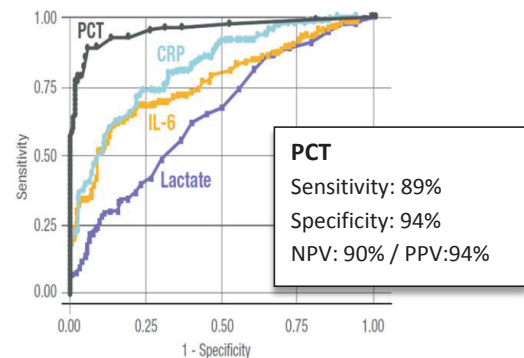
The ARCHITECT B·R·A·H·M·S PCT assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of procalcitonin (PCT) in human serum and plasma.

- Provides clinicians a risk assessment of critically ill patients on their first day of intensive care unit (ICU) admission for progression to severe sepsis and septic shock
- Aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock
- Aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis
- Excellent clinical sensitivity with an Limit of Quantitation (LoQ) of 0.0077 ng/mL allowing for early indication, antibiotic stewardship and negative predictive values

PROGRESSION LEVELS OF SEPSIS³



PCT PERFORMANCE VS COMPARABLE BIOMARKERS³



INTENDED USE AND IMPORTANT SAFETY INFORMATION

For *In Vitro* Diagnostics Use

Intended Use: The ARCHITECT B·R·A·H·M·S PCT assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of procalcitonin (PCT) in human serum and plasma (lithium heparin and K2EDTA) on the ARCHITECT *i*System.

Used in conjunction with other laboratory findings and clinical assessments, the ARCHITECT B·R·A·H·M·S PCT assay is intended for use as an: 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.

Aid in assessing the cumulative 28-day risk of all-cause mortality 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, using a change in PCT level over time.

Aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) – defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) – in an inpatient setting or an emergency department.

Aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.

See Important Safety Information on Reverse

SPECIFICATIONS⁶

METHOD & FORMAT	Two-step immunoassay using CMLA technology
THROUGHPUT/TIME TO FIRST RESULT	Up to 200 tests per hour on i2000 / 29 minutes
REAGENT ON-BOARD/ CALIBRATION STABILITY	25 days / Calibrate with new lot of QC out of range
ASSAY RANGE	0.02 to 100.00 ng/mL
SAMPLE VOLUME	Single test – 150 µL Additional test – 100 µL
SAMPLE TYPE	Human serum and plasma (Lithium Heparin and K2EDTA)
ASSAY SENSITIVITY*	LOB: 0.00 ng/mL LOD: 0.00 ng/mL LOQ: 0.01 ng/mL
ASSAY SPECIFICITY*	See package insert

*Representative data; Results in individual laboratories may vary from this data.

ORDERING INFORMATION⁶

PRODUCT DESCRIPTION	LIST NUMBER	CONFIGURATION
ARCHITECT B·R·A·H·M·S PCT Reagent	6P22-27 (100T) 6P22-37 (500T)	Each test kit contains: 1 bottle each (microparticles, conjugate, and diluent)
ARCHITECT B·R·A·H·M·S PCT Calibrator	6P22-01	6 Levels, A-F
ARCHITECT B·R·A·H·M·S PCT Control	6P22-10	Low (0.20 ng/mL), Medium (2.00 ng/mL), High (70.00 ng/mL)
ARCHITECT B·R·A·H·M·S PCT e-Assay File		www.abbottdiagnostics.com

AVAILABILITY ON SYSTEM
ARCHITECT i1000sR, i2000, i2000sR

REFERENCES:

1. Sepsis Alliance Website: http://www.sepsis.org/downloads/2017_sepsis_facts_media.pdf3.
2. Centers for Medicare & Medicaid Services website <https://data.medicare.gov/data/hospital-compare>.
3. Thermo Scientific B·R·A·H·M·S PCT Improving infection management.
4. Shiferaw, et al. The Role of Procalcitonin as a Biomarker in Sepsis. *J Infect Dis Epidemiology*. 2016;2:006 Vol 2.
5. Presentation entitled “Sepsis in the Rural Setting: Early Recognition and Management” by Mike Broyles, BS Pharm, PD, PharmD, Director of Pharmacy and Laboratory Services, Five Rivers Medical Center.
6. ARCHITECT B·R·A·H·M·S package inserts, G1-0601 R01, June 2017.

INTENDED USE AND IMPORTANT SAFETY INFORMATION (continued)

Warning:

- The ARCHITECT B·R·A·H·M·S PCT assay is not indicated to be used as a stand-alone diagnostic assay and should be used in conjunction with clinical signs and symptoms of infection and other diagnostic evidence.
- **Decisions regarding antibiotic therapy should NOT be based solely on PCT concentrations.**
- PCT results should always be interpreted in the context of the clinical status of the patient and other laboratory results. Changes in PCT levels for the prediction of mortality, and overall mortality, are 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 and SOFA score) are also significant predictors of 28-day cumulative mortality risk.
- Certain patient characteristics, such as severity of renal failure or insufficiency, may influence PCT values and should be considered as potentially confounding clinical factors when interpreting PCT values.
- PCT levels may not be elevated in patients infected by certain atypical pathogens, such as *Chlamydomydia pneumoniae* and *Mycoplasma pneumoniae*.
- **Low PCT levels do not always indicate absence of bacterial infection.** Falsely low PCT levels in the presence of bacterial infection may occur during the early course of infections, in localized infections, and in subacute infectious endocarditis.
- **Increased PCT levels may not always be related to systemic bacterial infection.**
- The safety and performance of PCT-guided therapy for individuals younger than age 18 years, pregnant women, immunocompromised individuals or those on immunomodulatory agents, was not formally analyzed in the supportive clinical trials.
- ARCHITECT B·R·A·H·M·S PCT results should not be used interchangeably with other methods for PCT determinations for monitoring patients.
- If the PCT results are inconsistent with clinical evidence, additional testing is recommended

Important Safety Information: Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in the package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

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