ACCESS PCT

EMPOWER FAST, ACCURATE CLINICAL DECISION-MAKING WHILE CONSOLIDATING YOUR WORKFLOW WITH THE ACCESS PCT ASSAY

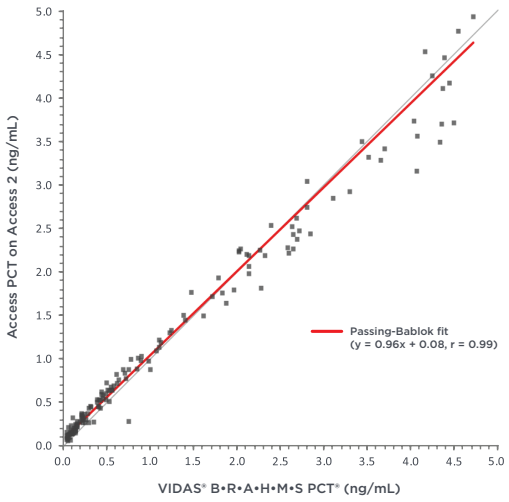
Background

Sepsis is a systemic inflammatory response to infection that can result in a number of life-threatening conditions, including organ dysfunction.[1] Despite advances in modern medicine, sepsis is still the primary cause of death from infection, causing an estimated 5.3 million deaths worldwide each year.[2]

Procalcitonin (PCT) is a 116 amino acid prohormone of calcitonin. PCT levels in healthy individuals are typically less than 0.1 ng/mL.[3] In individuals with inflammation or bacterial infections, PCT levels rise in circulation in response to bacterial endotoxins and inflammatory cytokines. PCT levels have been found to correlate with the severity of bacterial infections and also with the probability of a positive blood culture, making it a clinically useful marker in the assessment of patients with possible sepsis or septic shock.[1,4,5]

Access PCT provides confidence in results and improved patient care through:

- **>95% overall agreement with predicate method** for accurate assessment of patients for risk of progression to severe sepsis and septic shock
- **State-of-the art sensitivity and low-end precision**
  - 20% CV LoQ of 0.02 ng/mL
  - CV ≤8.0% at concentrations ≥0.150 ng/mL
- **Rapid access to results**—~20 minutes to first result
- **Minimal sample draw**—35 µL pickup volume



As part of Beckman Coulter's comprehensive assay menu, Access PCT offers laboratories the ability to simplify their sample-processing flow while reducing the operational expenses associated with maintaining a separate, dedicated workstation for PCT analysis.

Perform PCT testing as part of your routine workflow on Access immunoassay systems:

- Random-access, high-throughput systems with >65 available assays
- Reduced manual processing steps compared to standalone systems
- Onboard reagent storage of liquid, ready-to-use 50-test reagent packs
- 42-day calibration stability

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Interpretation of Results

PCT CONCENTRATION (ng/mL or µg/L)	INTERPRETATION
<0.5	LOW RISK OF SEVERE SEPSIS AND/OR SEPTIC SHOCK
≥0.5 to <2.0	MODERATE RISK OF PROGRESSION TO SEVERE SEPSIS AND/OR SEPTIC SHOCK
≥2.0	HIGH RISK OF SEVERE SEPSIS AND/OR SEPTIC SHOCK

PCT concentrations less than 0.5 ng/mL do not exclude local or systemic infections in their initial stages (under six hours). Consider the patient's history when interpreting PCT concentrations between 0.5 and 2.0 ng/mL. Retesting PCT within six to 24 hours is recommended if any concentrations are less than 2.0 ng/mL.[6]

Imprecision

The results below were generated from a study based on CLSI EP05-A3 guidelines utilizing three reagent lots, three calibrator lots and multiple calibrations. The study was run over 20 days, two runs per day in replicates of 2, for a total of 80 replicates per sample.

Sample	Average Concentration (ng/mL)	Total %CV
QC1	0.68	3.6
QC2	2.15	3.2
QC 3	20.65	3.2
Sample 1	0.090	7.2
Sample 2	0.18	5.6
Sample 3	0.27	4.4
Sample 4	0.43	5.7
Sample 5	1.41	5.0
Sample 6	7.59	4.2
Sample 7	76.31	3.8

Characteristics

Sample type/size	Serum, plasma (lithium heparin and EDTA)/35 µL
Approximate Calibrator Levels	0, 0.8, 5, 10, 25, 50 and 100 ng/mL (µg/L)
Analytical measuring range	0.01–100 ng/mL (µg/L), up to 1,000 ng/mL with Special Dilution Feature
Limit of Detection (LoD)	0.01 ng/mL (µg/L)
20% CV Limit of Quantitation (LoQ)	0.02 ng/mL (µg/L)
Imprecision	Total imprecision ≤8.0% CV at concentrations ≥0.150 ng/mL, and standard deviation (SD) ≤0.012 ng/mL at concentrations < 0.150 ng/mL
Open pack stability	42 days
Calibration stability	42 days
Time to first result (approx.)	20 minutes

Ordering information

Access PCT (2 packs of 50 tests/pack)	**C22593**
Access PCT Calibrators (S0-S6, 1 vial/level of 2.0 mL/vial (lyophilized))	**C22594**

References

1. Wacker C, Prkno A, Brunkhorst FM, Schlattmann P (2013) Procalcitonin as a diagnostic marker for sepsis: a systematic review and meta-analysis. Lancet Infect Dis. 13(5):426–435.
2. Fleischmann C, Scherag A, Adhikari NK, et al. Assessment of Global Incidence and Mortality of Hospital-treated Sepsis. Current Estimates and Limitations. Am J Respir Crit Care Med 2016; 193(3): 259-72.
3. Maruna P, Nedelnikova K, Gurlich R: Physiology and Genetics of Procalcitonin. Physiol Res 2000; 49(Suppl1):S57–S61.
4. Schuetz P, Bretscher C, Bernasconi L, and Mueller, B. Overview of procalcitonin assays and procalcitonin-guided protocols for the management of patients with infections and sepsis. Expert Rev Mol Diagn, 2017. vol. 17, No. 6, 593–601.
5. Clementine YF, Yap, Tar Choon Aw. The Use of Procalcitonin in Clinical Practice. Proceedings of Singapore Healthcare, Volume 23, Number 1, 2014.
6. Meisner M, Procalcitonin — Biochemistry and Clinical Diagnosis, ISBN 978-3-8374-1241-3, UNI-MED, Bremen 2010.

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