Test Definition: PCT

Procalcitonin, Serum

Overview

Useful For

Aiding in the risk assessment of critically ill patients on their first day of intensive care unit admission for progression to severe sepsis and septic shock

Aiding in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock

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

Method Name

Homogeneous Time-Resolved Fluorescence

NY State Available

Yes

Specimen

Specimen Type

Serum Red

Specimen Required

Collection Container/Tube: Red top (serum gel/SST are **not acceptable**)
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.25 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum Red	Refrigerated (preferred)	7 days	

	Frozen	90 days	

Clinical & Interpretive

Clinical Information

Procalcitonin (ProCT) is a 116-amino acid precursor of calcitonin (CT). ProCT is processed to an N-terminal 57 amino acid peptide (CT [32-amino acids] and a 21-amino acid C-terminal peptide, catacalcin [CCP-1]). Expression of this group of peptides is normally limited to thyroid C cells and, to a small extent, other neuroendocrine cells. CT is the only hormonally active of these peptides. CT is secreted by C cells in response to hypercalcemia and inhibits bone resorption by osteoclasts, minimizing oscillations in serum calcium and calcium loss.

During severe systemic inflammation, particularly those related to bacterial infection, the tissue-specific control of CT-related peptides expression breaks down and ProCT and CCP-1 (referred collectively to as ProCT) are secreted in large quantities by many tissues. CT levels do not change.

ProCT concentrations rise rapidly (within 6-12 hour) after an infectious bacterial insult with systemic consequences. ProCT secretion parallels the severity of the inflammatory insult, with higher concentrations associated with more severe disease and declining concentrations with resolution of illness. In the absence of an ongoing stimulus, ProCT is eliminated with a half-life of 24 hours.

Reference Values

Adults and children > or =72 hours: < or =0.15 ng/mL
Children <72 hours old: <2.0 ng/mL at birth, rises to < or =20 ng/mL at 18-30 hours of age, then falls to < or =0.15 ng/mL by 72 hours of age

Interpretation

Progression to Severe Sepsis and Septic Shock:
This assay is intended 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. Systemic inflammatory response syndrome, sepsis, severe sepsis, and septic shock were categorized according to the criteria of the consensus conference of the American College of Chest Physicians/Society of Critical Care Medicine.(1)

In the appropriate clinical setting, procalcitonin (ProCT) concentrations above 2.0 ng/mL on the first day of admission to the ICU represent a high risk for progression to severe sepsis and/or septic shock. ProCT concentrations below 0.50 ng/mL on the first day of ICU admission represent a low risk for progression to severe sepsis and/or septic shock. ProCT concentrations below 0.5 ng/mL do not exclude an infection; localized infections (without systemic signs) may also be associated with such low ProCT concentration. If the ProCT measurement is done very early after the systemic infection process has started (usually less than 6 hours), these values may still be low.

Various noninfectious conditions are known to induce changes in ProCT level. ProCT levels between 0.5 ng/mL and 2.0 ng/mL should be interpreted in the context of the specific clinical background and condition of the individual patient.

28-day Risk of All-Cause Mortality:
The change in ProCT concentration over time provides prognostic information about the risk of mortality within 28 days

for patients diagnosed with severe sepsis or septic shock. Data supports the use of procalcitonin determinations from the day severe sepsis or septic shock is first diagnosed (day 0) or the day thereafter (day 1) and the fourth day after diagnosis (day 4) for the classification of patients into higher and lower risk for mortality within 28 days.

A ProCT concentration that decreases less than or equal to 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 a higher risk for 28-day all-cause mortality of patients diagnosed with severe sepsis or septic shock.

A ProCT concentration that decreases more than 80% from the day that severe sepsis or septic shock was clinically diagnosed (day 0) to 4 days after clinical diagnosis (day 4) is associated with a lower risk for 28-day all-cause mortality of patients diagnosed with severe sepsis or septic shock.

Discontinuation of Antibiotic Therapy:
With successful antibiotic therapy, ProCT levels should fall with a half-life to 24 hours.

Several randomized controlled trials have demonstrated the use of ProCT to guide discontinuation of antibiotic therapy in patients with acute respiratory tract infection significantly reduces antibiotic consumption. This reduction of antibiotic consumption was clinically safe without an increase in mortality rates or treatment failure.

Similarly, randomized controlled trials demonstrated the ability of ProCT to guide the discontinuation of antibiotic therapy in the case of sepsis. The Stop Antibiotics on Procalcitonin Guidance Study showed a reduction in the duration of antibiotic therapy for patients with suspected or confirmed infection from 7 days in the standard-of-care group to 5 days in the ProCT-guided group and a reduction of 5.4% in 28-day mortality from 25% to 19.6%.

ProCT Interpretations in Pediatric Populations:
Diagnosis of bacteremia in neonates: After birth, ProCT values increase to reach peak values at about 24 hours of life and then decrease gradually by 48 hours of life. Therefore, during the first 72 hours of life different reference ranges will apply to newborn infants at different hours of age. ProCT levels on newborns suffering from early sepsis are significantly higher than those of noninfected newborns when reference ranges by hours of age are used.(1,2) Adult levels should apply at 72 hours or more after birth.

Increased ProCT levels may not always be related to systemic infection. Conditions that may result in increased ProCT concentrations include, but are not limited to:
-Patients experiencing major trauma or recent surgical procedure, including extracorporeal circulation or burns
-Patients under treatment with OKT3 antibodies, OK-432, interleukins, tumor necrosis factor-alpha, and other drugs stimulating the release of proinflammatory cytokines or resulting in anaphylaxis
-Patients diagnosed with active medullary C-cell carcinoma, small cell lung carcinoma, or bronchial carcinoid
-Patients with acute or chronic viral hepatitis or decompensated severe liver cirrhosis (Child-Pugh Class C)
-Patients with prolonged or severe cardiogenic shock, prolonged severe organ perfusion anomalies, or after resuscitation from cardiac arrest
-Patients receiving peritoneal dialysis or hemodialysis treatment
-Patients with biliary pancreatitis, chemical pneumonitis, or heat stroke
-Patients with invasive fungal infections (eg, candidiasis, aspergillosis) or acute attacks of plasmodium falciparum malaria
-Neonates during the first 2 days of life

Cautions

Procalcitonin (ProCT) 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.

Severe trauma, major burns, multiorgan failure, or major surgery can cause ProCT elevations in the absence of sepsis. After removal of the noxious stimulus, ProCT should start to decrease.

Patients with untreated kidney failure may have ProCT levels greater than 0.15 ng/mL in the absence of infection or severe inflammation. Within 3 hemodialysis treatments, this should fall to the normal reference range. Patients with kidney failure who are on stable hemodialysis or peritoneal dialysis treatments have ProCT levels similar to healthy adults with normal kidney function.

Patients with medullary thyroid carcinoma or, very rarely, islet cell tumors may have significant elevations in ProCT in the absence of sepsis. In certain cases, these levels may exceed 10,000 ng/mL.

Some infants and children may have ProCT levels from 0.15 ng/mL to 0.50 ng/mL for unknown reasons.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Bone RC, Balk RA, Cerra FB, et al. Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. The ACCP/SCCM Consensus Conference Committee. American College of Chest Physicians/Society of Critical Care Medicine. Chest. 1992;101(6):1644-1655. doi:10.1378/chest.101.6.1644
2. Chiesa C, Panero A, Rossi N, et al. Reliability of procalcitonin concentrations for the diagnosis of sepsis in critically ill neonates. Clin Infect Dis. 1998;26(3):664-672
3. Chiesa C, Natale F, Pascone R, et al. C reactive protein and procalcitonin: reference intervals for preterm and term newborns during the early neonatal period. Clin Chim Acta. 2011;412(11-12):1053-1059
4. van Rossum AM, Wulkan RW, Oudesluys-Murphy AM. Procalcitonin as an early marker of infection in neonates and children. Lancet Infect Dis. 2004;4(10):620-630
5. Hamade B, Huang DT. Procalcitonin: Where are we now? Crit Care Clin. 2020;36(1):23-40. doi:10.1016/j.ccc.2019.08.003
6. Atallah NJ, Warren HM, Roberts MB, et al. Baseline procalcitonin as a predictor of bacterial infection and clinical outcomes in COVID-19: A case-control study. PLoS One. 2022;17(1):e0262342. doi:10.1371/journal.pone.0262342
7. Metlay JP, Waterer GW, Long AC, et al. Diagnosis and treatment of adults with community-acquired pneumonia. An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med. 2019;200(7):e45-e67. doi:10.1164/rccm.201908-1581ST
8. Chambliss AB, Patel K, Colon-Franco JM, et al. AACC Guidance Document on the Clinical Use of Procalcitonin. J Applied Lab Med. 2023;8(3):598-634

Performance

Method Description

Procalcitonin (ProCT) is measured in this homogeneous automated immunofluorescent assay on the BRAHMS Kryptor. The Kryptor uses TRACE (time resolved amplified cryptate emission) technology based on a nonradioactive transfer of energy. This transfer occurs between 2 fluorescent tracers: the donor (europium cryptate) and the acceptor (XL665). In the ProCT assay, a sheep polyclonal antibody against calcitonin is labeled with europium cryptate and a mouse monoclonal antibody against catacalcin is labeled with XL665. ProCT is sandwiched between the 2 antibodies, bringing them into close proximity. When the antigen-antibody complex is excited with a nitrogen laser at 337 nm, some fluorescent energy is emitted at 620 nm, and the rest is transferred to XL665. This energy is then emitted as fluorescence at 665 nm. A ratio of the energy emitted at 665 nm to that emitted at 620 nm (internal reference) is calculated for each sample. Signal intensity is proportional to the number of antigen-antibody complexes formed, and therefore to antigen concentration.(Package insert: BRAHMS PCT Sensitive Kryptor. Thermo Fisher Scientific BRAHMS LLC; Version 18.Ous, 2017)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

2 weeks

Performing Laboratory Location

Rochester

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

84145

LOINC® Information

Test Definition: PCT

Procalcitonin, Serum

Test ID	Test Order Name	Order LOINC® Value
PCT	Procalcitonin, S	33959-8

Result ID	Test Result Name	Result LOINC® Value
PCT	Procalcitonin, S	33959-8