MAYO CLINIC LABORATORIES

Test Definition: PRCAL

Procalcitonin, Serum

Overview

Useful For

Monitoring antibiotic therapy and all-cause mortality for patients diagnosed with severe sepsis or septic shock in the Intensive Care Unit (ICU) or when obtained in the emergency department or other medical wards prior to ICU admission

Method Name

Electrochemiluminescence

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Specimen Volume: 0.6 mL
Collection Instructions:
1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged and the serum aliquoted into a plastic vial within 2 hours of collection.

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	90 days	
	Ambient	24 hours	

	Refrigerated	48 hours	

Clinical & Interpretive

Clinical Information

Procalcitonin (PCT) is a biomarker associated with the inflammatory response to bacterial infection and aids in the risk assessment of critically ill patients on their first day of admission to the intensive care unit (ICU), or when obtained in the emergency department or other medical wards prior to ICU admission, for progression to severe sepsis and septic shock. The percent change in PCT level over time aids in the prediction of cumulative 28-day mortality in patients with severe sepsis and septic shock.

A PCT level that declines 80% or less 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 higher cumulative 28-day risk of all-cause mortality than a decline above 80%.

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.

Reference Values

0.00-0.24 ng/mL

Interpretation

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)

The change of procalcitonin (PCT) concentration over time provides prognostic information about the risk of mortality(2) within 28 days for patients diagnosed with severe sepsis or septic shock coming from the emergency department, intensive care unit, other medical wards, or directly from outside the hospital. Data support 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.

Change in procalcitonin of 80% or less:
A decrease of PCT levels below or equal to 80% defines a positive change in PCT test result representing a higher risk for 28-day all-cause mortality of patients diagnosed with severe sepsis or septic shock.

Change in procalcitonin above 80%:
A decrease of PCT levels of more than 80% defines a negative change in PCT result representing a lower risk for 28-day all-cause mortality of patients diagnosed with severe sepsis or septic shock.

Positive results:
Procalcitonin greater than or equal to 0.25 ng/mL may indicate bacteremia or bacterial pneumonia; however, it is a non-specific biomarker. False positives can be seen in patients with a variety of illnesses, including but not limited to severe trauma, shock, recent surgery, burns, renal insufficiency, severe liver disease, COVID-19, and certain malignancies.

Negative results:
Procalcitonin less than 0.25 ng/mL may indicate lower probability of bacteremia or bacterial pneumonia. Intracellular bacteria, viruses, and fungi do not cause elevation of procalcitonin, so low values (<0.25 ng/mL) do not rule out other infections.

Cautions

This assay is not indicated to be used as a stand-alone diagnostic assay to determine the risk of 28-day all-cause mortality. Changes in procalcitonin 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 procalcitonin 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 intensive care unit care at day 4 and other covariates (eg, age, SOFA score) are also significant predictors of 28-day cumulative mortality risk.

Validation of this test as an aid in predicting mortality was performed in a study population with an overall 28-day mortality of 22%.

Serum biotin concentrations up to 1200 ng/mL do not interfere with this assay. Concentrations up to 1200 ng/mL may be present in specimens collected from patients taking extremely high doses of biotin up to 300 mg per day.(3) In a study among 54 healthy volunteers, supplementation with 20 mg/day biotin resulted in a maximum serum biotin concentration of 355 ng/mL 1 hour post-dose.(4)

Clinical Reference

1. American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference: Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. Crit Care Med. 1992;20(6):864-874
2. Schuetz P, Maurer P, Punjabi V, Desai A, Amin DN, Gluck E. Procalcitonin decrease over 72 hours in US critical care units predicts fatal outcome in sepsis patients. Crit Care. 2013;17(3):R115. doi:10.1186/cc12787
3. Peyro Saint Paul L, Debruyne D, Bernard D, Mock DM, Defer GL. Pharmacokinetics and pharmacodynamics of MD1003 (high-dose biotin) in the treatment of progressive multiple sclerosis. Expert Opin Drug Metab Toxicol. 2016;12(3):327-344. doi:10.1517/17425255.2016.1136288
4. Grimsey P, Frey N, Bendig G, et al. Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. J Pharmacokinet Pharmacodyn. 2017;2(4):247-256. doi:10.4155/ipk-2017-0013
5. Chambliss AB, Patel K, Colon-Franco JM, et al. AACC guidance document on the clinical use of procalcitonin. J Appl Lab Med. 2023;8(3):598-634. doi:10.1093/jalm/jfad007

Performance

Method Description

The procalcitonin method employs monoclonal antibodies specifically directed against procalcitonin. A biotinylated monoclonal antibody and a second monoclonal antibody labeled with a ruthenium complex react to form a sandwich complex. After the addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles

are magnetically captured onto the surface of the electrode. Application of a voltage to the electrode then induces chemiluminescent emission, that is measured by a photomultiplier.(Package insert: PCT. Roche Diagnostics; 04/2023)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 2 days

Specimen Retention Time
7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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

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