

 $\mathsf{Q}$   $\$  Use a keyword, test name or number

## Procalcitonin

TEST: 164750	CPT: 84145
Synonyms	• PCT
Special	This test may exhibit interference when sample is collected from a person who is consuming a
Instructions	supplement with a high dose of biotin (also termed as vitamin B7 or B8, vitamin H, or
	coenzyme R). It is recommended to ask all patients who may be indicated for this test about
	biotin supplementation. Patients should be cautioned to stop biotin consumption at least 72
	hours prior to the collection of a sample.
Expected	2 - 3 days
Turnaround	Turnaround time is defined as the usual number of days from the date of nickup of a specimen for testing to when the result
Time	is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.
Related	<u>Sample Report</u>
Documents	
SPECIMEN REQ	UIREMENTS
Specimen	Serum <b>or</b> plasma, <b>frozen</b>
Volume	0.8 mL
Minimum	0.5 mL ( <b>Note:</b> This volume does <b>not</b> allow for repeat testing.)
Volume	
Container	Red-top tube, gel-barrier tube, green-top (lithium heparin) tube, <b>or</b> lavender-top (EDTA) tube

	submit separate frozen specimens for each test requested.
	To avoid delays in turnaround time when requesting multiple tests on frozen samples, <b>please</b>
Collection	Separate serum or plasma from cells and transfer to a plastic transport tube before freezing.

StorageFreeze; stable at room temperature for 24 hours. Stable refrigerated for 48 hours or frozen forInstructionsthree months. Freeze/thaw cycles: stable x1.

## TEST DETAILS

Use Used in conjunction with other laboratory findings and clinical assessments, Elecsys BRAHMS PCT is intended for use as follows<sup>11</sup>:

• to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock;

• to determine the change in PCT level over time as an 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;

• to aid in decision making on antibiotic therapy, for inpatients or patients in the emergency department 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);

• to aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.

Limitations The Elecsys BRAHMS PCT 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. In cases where the laboratory results do not agree with the clinical picture or history, additional tests should be performed. Changes in PCT should always be interpreted in the context of the clinical status of the patient and other laboratory results. Decisions regarding antibiotic therapy should **not** be based solely on procalcitonin concentrations.

> 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 Elecsys BRAHMS PCT test as an aid in predicting mortality was performed in a study population with an overall 28-day mortality of 22%.

Certain patient characteristics, such as severity of renal failure or insufficiency, may influence procalcitonin values and should be considered as potentially confounding clinical factors when interpreting PCT values. Increased PCT levels may be observed in severe illness such as polytrauma, burns, major surgery, prolonged or cardiogenic shock. PCT levels may not be elevated in patients infected by certain atypical pathogens, such as Chlamydia pneumoniae and Mycoplasma pneumoniae. The safety and performance of PCT-guided therapy for individuals younger than age 17 years, pregnant women, immunocompromised individuals or those on immunomodulatory agents, was not formally analyzed in the supportive clinical trials.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Increased PCT levels may not always be related to systemic infection.<sup>4,15-17</sup> These include, but are not limited to:

• Patients experiencing major trauma and/or recent surgical procedure including extracorporeal circulation or burns;

• Patients undergoing treatment with OKT3 antibodies, OK-432, interleukins, TNF-alpha and other drugs that stimulate the release of pro-inflammatory cytokines or result in anaphylaxis;

• Patients diagnosed with active medullary C-cell carcinoma, small cell lung carcinoma, or bronchial carcinoid;

• Patients with acute or chronic viral hepatitis and/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 (e.g., candidias aspergillosis) or acute attacks of plasmodium falciparum malaria;

• Neonates during the first 2 days of life.

Methodology Electrochemiluminescence immunoassay (ECLIA)

Additional PCT is the prohormone of the hormone calcitonin, but PCT and calcitonin are distinct Information proteins. Calcitonin is exclusively produced by C-cells of the thyroid gland in response to hormonal stimuli, whereas PCT can be produced by several cell types and many organs in response to proinflammatory stimuli, in particular by bacterial products.<sup>1</sup>

In healthy people, plasma PCT concentrations are found to be below  $0.1 \,\mu\text{g/L}.^2$  Depending on the clinical background, a PCT concentration above  $0.1 \,\mu\text{g/L}$  can indicate clinically relevant bacterial infection, requiring antibiotic treatment.<sup>3</sup> PCT levels rise rapidly (within 6 to 12 hours) after a bacterial infectious insult with systemic consequences. The magnitude of the increase in PCT concentration correlates with the severity of the bacterial infection.<sup>4</sup> At a PCT concentration >0.5  $\mu$ g/L, a patient should be considered at risk of developing severe sepsis or septic shock.<sup>5,6</sup> On the other hand, the relief of the septic infection is accompanied by a decrease in the PCT concentration which returns to normal with a half-life of 24 hours,<sup>7,8</sup> (ie, the continuous decline of PCT is indicative of effective source control measures and has been implicated in the safe deëscalation of antibiotic therapy).<sup>9,10</sup>

Data support the following interpretative risk assessment criteria<sup>11,12,13</sup>:

PCT > 2 ng/mL: A PCT level above 2.0 ng/mL on the first day of ICU admission is associated with a high risk for progression to severe sepsis and/or septic shock.

PCT < 0.5 ng/mL: A PCT level below 0.5 ng/mL on the first day of ICU admission is associated with a low risk for progression to severe sepsis and/or septic shock.

Note: Concentrations < 0.5 ng/mL do not exclude an infection, on account of localized infections (without systemic signs) which can be associated with such low concentrations, or a systemic infection in its initial stages (< 6 hours).

Furthermore, increased procalcitonin can occur without infection. PCT concentrations between 0.5 and 2.0 ng/mL should be interpreted taking into account the patient's history. It is recommended to retest PCT within 6-24 hours if any concentrations < 2 ng/mL are obtained.

The change of PCT concentration over time (Delta PCT) provides prognostic information about the risk of mortality<sup>14</sup> within 28 days for patients diagnosed with severe sepsis or septic shock coming from the emergency department, ICU, other medical wards, or directly from outside the hospital. Data support the use of PCT 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. The Delta PCT is calculated in the manufacturer's package insert for the Elecsys BRAHMS PCT<sup>11</sup> as:

The change in PCT (Day 0 value minus Day 4 value) divided by the Day 0 value, all multiplied by 100%.

This calculated result is interpreted as follows:

Delta PCT  $\leq$  80 %: A decrease of PCT levels below or equal to 80 % defines a positive  $\Delta$ PCT test result representing a higher risk for 28-day all-cause mortality of patients diagnosed with severe sepsis or septic shock.

Delta PCT > 80 %: A decrease of PCT levels of more than 80 % defines a negative ΔPCT result representing a lower risk for 28-day, all-cause mortality of patients diagnosed with severe sepsis or septic shock.

Notes:

• If Day 0 result is not available, Day 1 result may be used.

• If more than one PCT value is available on Day 0 (or Day 1), enter the highest value.

• If more than one PCT value is available on Day 4, enter the most recent value.

 Footnotes
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