



High-Q Procalcitonin (PCT) Assay (Latex Enhanced Turbidimetric Immuno Assay) (LETIA)

Two Liquid Stable Reagents
4 Level Calibrators
2 Level Controls (Optional)

Features and Benefits:

- Latex Enhanced Turbidimetric Immuno Assay (LETIA)
- Results comparable to CLIA and IFA
- Fast test results (8 minutes) for a rapid turnaround time.
- Reagent on-board stability: Six weeks
- Wide range of instrument programs available
- Liquid stable two reagents
- 4 Level liquid stable calibrators provided
- 2 Level liquid stable controls provided (Optional)
- Measuring wavelength 630 nms (600-630)
- Linearity 60 ng/mL

Sensitive
Specific
Reliable
Trustworthy
Sepsis Marker



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Biotech**
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Summary:

Procalcitonin (PCT) is a 116 amino acid protein, the prohormone of calcitonin. Whereas hormonally active calcitonin is produced exclusively in the C-cells of the thyroid gland after specific intracellular proteolytic procession of the prohormone PCT. PCT is ubiquitously and uniformly expressed in multiple tissues throughout the body in response to sepsis. In healthy conditions, the PCT levels in circulation are very low (<0.05 ng/mL).

Procalcitonin (PCT) is a marker for bacterial infection and sepsis. Procalcitonin (PCT) levels elevate during systemic bacterial infection and sepsis.

The High-Q Procalcitonin (PCT) Assay can be used in conjunction with other tests to quickly assess initial severity of sepsis.

The High-Q Procalcitonin (PCT) Assay is precise, convenient and cost effective and It is available in a liquid-stable format which can be performed on Clinical Chemistry Analyzer for up to six weeks (Onboard Stability)

Principle:

High-Q PCT Assay is a Latex Enhanced Turbidimetric Immuno Assay (LETIA) intended for the quantitative determination of Procalcitonin in human serum, EDTA or lithium heparin plasma. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock. PCT proteins in the sample bind to the specific anti-PCT antibody, which is coated on latex particles and causes agglutination.

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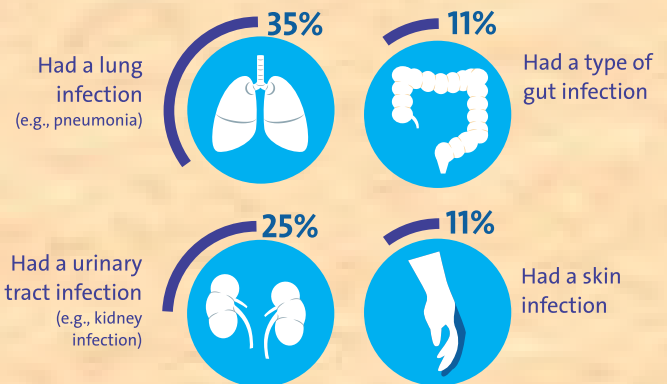
Definitions

Definitions for the terms of "SIRS", "sepsis", "severe sepsis" or "septic shock" have been proposed by the ACCP/SCCM consensus conference in 1992, and are now widely used (see below table 1).

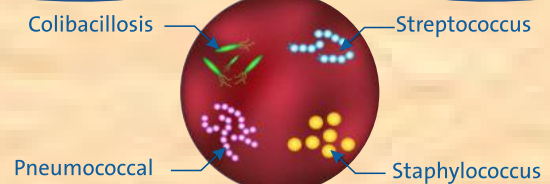
SIRS and sepsis definition (ACCP/SCCM-criteria) SIRS (Systemic Inflammatory Response Syndrome)	2 or more of the following criteria: • Temperature > 38°C or < 36°C • Heart rate > 90 beats/min • Respiratory rate > 20 breaths/min or PaCO ₂ < 32 mm Hg (<4.3 kPa) • WBC > 12 000 cells/μL or < 4 000 cells/ μL or > 10% immature (band) forms
Sepsis	Documented infection together with 2 or more SIRS criteria
Severe Sepsis	Sepsis associated with organ dysfunction including, but not limited to, lactic acidosis, oliguria, hypoxemia, coagulation disorders, or an acute alteration in mental status.
Septic Shock	Sepsis with hypotension, despite adequate fluid resuscitation along with the presence of perfusion abnormalities. Patients who are on inotropic or vasopressor agents may not be hypotensive at the time when perfusion abnormalities are detected.

Common infections can lead to sepsis

Among adults with sepsis



Example of Sepsis Causing Bacteria





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Fast and highly specific PCT increase in bacterial infection and sepsis:

One major advantage of PCT compared to other parameters is its early and highly specific increase in response to severe systemic bacterial infections and sepsis. Therefore in septic conditions increased PCT Levels can be observed 3-6 hours after an infectious challenge..

PCT levels are usually low in viral infections chronic inflammatory disorders or auto immune disorders. PCT levels in sepsis are generally greater than 0.5-2 ng/mL and often reach values between 10 and 100 ng/mL, or considerably higher in individual cases, thereby enabling diagnostic differentiation between these various clinical conditions and a severe bacterial infection (Sepsis)

Result Interpretation:

According to the criteria of the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference, diagnosis of systemic bacterial infection sepsis is categorized as follows:

PCT < 0.5 ng/mL:

Systemic infection (Sepsis) is not likely, Local bacterial infection may be possible.

PCT ≥ 0.5 ng/mL and 2 ng/ml:

infection is possible but other non bacterial conditions are known to increase PCT as well. Should be clinically correlated before starting antibiotic treatment

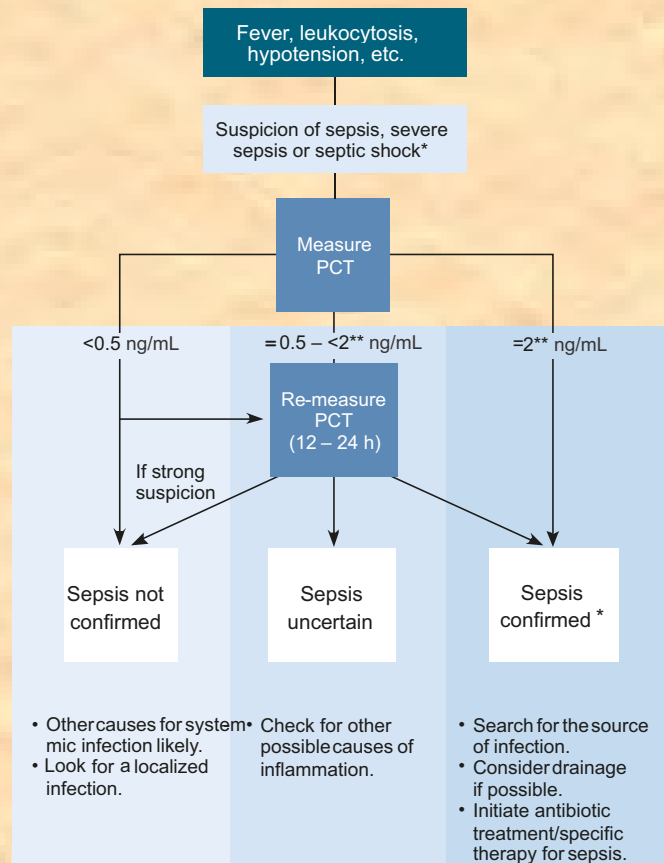
PCT ≥ 2 ng/mL and < 10 ng/ml:

Systemic infection (sepsis) is likely, unless other causes are known; High risk for progression to severe systemic infection (Severe Sepsis)

PCT ≥ 10 ng/ml:

important systemic inflammatory response, due to severe bacterial or septic shock

Sepsis diagnosis with PCT



* In the absence of non-infectious causes for induction of PCT

The cut off of 2 ng/mL given in the scheme is for orientation purpose only. Each clinical department should adapt it according to its patients' population. Cut off may be at PCT level higher or lower than 2 ng/mL depending on patient's background. Example: Major Surgery (Higher) or Patient in medical ICU (Lower)

Clinical Limitations and Correlations:

Increased PCT levels may not always be related to systemic bacterial infection

Several situations have been described where PCT can be elevated due to non bacterial causes also. These include, but are not limited to:

Neonates < 48 hours of life (Physiological Elevation)
The initial days after major trauma, major surgical intervention, severe burns, treatment with OKT3 antibodies and other drugs stimulating the release of pro-inflammatory cytokines

Patients with invasive fungal infections, acute attacks of Plasmodium falciparum malaria, Patients with prolonged or severe cardiogenic shock, Prolonged severe organ perfusion anomalies, Small cell lung cancer, Medullary C-Cell carcinoma of the thyroid.

Low PCT levels do not automatically exclude the presence of bacterial infection.

Such low levels may be obtained, during the early course of infections, in localized infections and in sub acute endocarditis. Therefore, follow-up and re-evaluation of PCT in clinical suspicion of infection is pivotal. The PCT measuring technique should be chosen according to clinical use.

Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.



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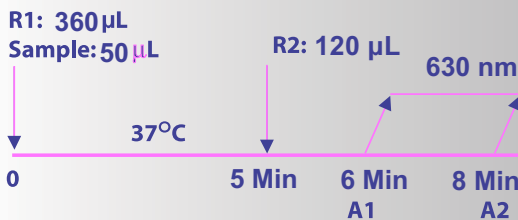
Command on Quality

Assay Specifications:

Method	Latex Enhanced Turbidimetric Immuno Assay LETIA
Sample Type & Volume	<ul style="list-style-type: none"> Serum Plasma - EDTA - Li-heparin <p>Sample Volume 30 μL</p>
Method Comparison	<p>Regular Regression: N = 219 y-intercept = -0.225 Slope = 1.041 R² = 0.9837</p> <p>Sample Range = 0.21 - 51.26 ng/mL</p>
Linearity	Up to 60 ng/mL
LOB LOD LOQ	<p>0.06 ng/mL</p> <p>0.16 ng/mL</p> <p>0.20 ng/mL*</p>
Calibration Levels	4-Point Calibration
Reagent On-Board Stability	<p>Opened:</p> <p>Six Weeks on board analyzer</p>

*Results below 0.20 ng/mL are reported as < 0.20 ng/mL

PCT Assay Procedure**



**Analyzer Dependent

1. Dipalo, Mariella, Lorena Guido, Gianmatteo Micca, Salvatore Pittalis, Massimo Locatelli, Andrea Motta, Vincenza Bianchi, Tiziana Callegari, Rosalia Aloe, Giorgio Da Rin, and Giuseppe Lippi. "Multicenter Comparison of Automated Procalcitonin Immunoassays." Practical Laboratory Medicine 2 (2015): 22-28. Web.

Assay Precision:

The precision of the High-Q PCT Assay was evaluated according to CLSI EP5-A2 guidelines. In the study, six serum samples and 2 levels of serum based controls were tested in duplicate per run, 2 runs per day for 20 days using three lots of the reagents. The results of the within-run, between-run, between-day, between-lot, and total CV% for three lots of the reagent combined are listed in the following table (N=240):

Internal Precision

Sample	Mean ng/mL	Within-Run SD/CV%	Between-Run SD/CV%	Between-Day SD/CV%	Between-lot SD/CV%	Total SD/CV%
S1	0.27	0.034 / 12.3%	0.027 / 10.0%	0.019 / 6.9%	0.047 / 17.3%	0.047 / 17.3%
S2	0.48	0.035 / 7.3%	0.033 / 6.8%	0.031 / 6.4%	0.057 / 11.8%	0.057 / 11.9%
S3	1.80	0.062 / 3.4%	0.032 / 1.8%	0.059 / 3.2%	0.09 / 5.0%	0.091 / 5.0%
S4	5.30	0.085 / 1.6%	0.140 / 2.6%	0.130 / 2.5%	0.21 / 3.9%	0.209 / 4.0%
S5	23.56	0.058 / 2.5%	0.482 / 2.0%	0.891 / 3.8%	1.20 / 5.1%	1.168 / 5.0%
S6	47.65	0.069 / 1.5%	0.712 / 1.5%	0.657 / 1.4%	1.18 / 2.5%	1.196 / 2.5%
Con 1	1.16	0.046 / 4.0%	0.038 / 3.3%	0.031 / 2.7%	0.07 / 5.8%	0.068 / 5.8%
Con 2	18.30	0.477 / 2.6%	0.126 / 0.7%	0.751 / 4.1%	0.88 / 4.8%	0.899 / 4.9%

Assay Interference:

The following substances normally present in the samples produced less than 10 deviation when tested at levels equal to the concentrations listed below.

Interference Substances	Concentration	Interference Substances	Concentration
Ascorbic acid	129 mg/dL	Albumin	4 g/dL
Free Bilirubin	30 mg/dL	Human Calcitonin	60 ng/mL
Bilirubin Conjugated	30 mg/dL	Human Katalcacin	10 ng/mL
Hemoglobin	750 mg/dL	Human alpha-CGRP	10 μ g/mL
Triglyceride	750 mg/dL	Human beta-CGRP	10 μ g/mL
Rheumatoid Factor	75 IU/mL	Human Anti-mouse IgG (HAMA)	350 ng/mL

The following therapeutic drugs showed no significant interference (\pm 10%) up to the concentrations summarized below.

Tested Drugs	Concentration	Tested Drugs	Concentration
Imipenem	0.5 mg/mL	unfractionated Heparin	16,000 U/L
Cefotaxime	180 mg/dL	Furosemide	4 mg/dL
Noradrenalin	4 μ g/mL	Vancomycin	3 mg/mL
Dobutamine	22.4 μ g/mL	Dopamine	26 mg/dL



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