High-Q Procalcitonin (PCT)

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

Intended Use: Kit for the In Vitro quantitative determination of Procalcitonin in Human Serum or Plasma

Pariksha Biotech
A game changer in IVD

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Intended Use

High-Q Procalcitonin Reagent Kit
is a Latex-Enhanced Turbidimetric Assay intended for *in vitro* quantitate detection of Procalcitonin in human serum or plasma on automated clinical chemistry analyzers.

Summary and Explanation

Procalcitonin (PCT) is a 116 amino acid protein, the prohormone of calcitonin. Whereas hormonally acti e 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 issues throughout the body in response to sepsis [1]. In healthy conditions, the PCT levels in the circulation are very low (< 0.05 ng/ml). Elevated to circulating levels of PCT are important indicators in response to microbial infections and a powerful tool in the early detection of s epsis. According to the criteria of the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conferencea, rediagnosis of systemic bacterial infection sepsis is categorized as follows: PCT < 0.5 ng/mL: systemic infection (sepsis) is not likely, local bacterial infection is possible; PCT ≥ 0.5 ng/mL and < 2 ng/mL: systemic infection (sepsis) is possible but other conditions known to increase PCT as well; PCT ≥ 2 ng/mL and < 10 ng/mL: systemic infection (sepsis) is likely, unless other cause are known; PCT ≥ 10 ng/mL, important systemic inflammatory response, almost exclusively due to severe bacterial or septic shock.
Deferential diagnosis of lower respiratory tract infections: PCT < 0.25 ng/mL: bacterial infection unlikely. Use of antibook is discouraged; PCT ≥ 0.25 ng/mL and < 0.5 ng/mL: bacterial infection is possible. Recommendation to initiate antimicrobial therapy; PCT ≥
0.5 ng/mL: suggests the presence of bacterial infection. Antibiotic treatment strongly recommended.

Test Principle

The Kit utilizes latex -enhanced immunoturbidimetry to measure the PCT level in human serum or plasma. During the test, PCT in the sample binds with the antibody that is coated on latex parties to cause agglutinin. The turbidity caused by agglutinant is detected optically by chemistry analyzer at wavelength of 630 nm. The change in absorbance is proportional to the level of PCT in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

Reagents:

R1	Tris Buffer solution	(0.2 mol/L)
	Nacl	(6.0 g/L)
	PEG-6000	(22 g/L)
R2	Suspension of anti-human PCT monoclonal antibody coated latex particles	(0.3%)
	Phosphate Buffered Saline (ph=7.00)	(0.2 mol/L)
	BSA	(3 g/L)
	Tween20	(3 mL/L)

2. PCT calibrator set is provided along with the Reagent Kit
PCT Control set is purchased optional.

Specimen Collection and Handling

Follow standard laboratory procedures to collect serum or lithium heparin and EDTA plasma samples.
It is recommended to perform test immediately after sample collection to avoid hemolysis. If the test cannot be done immediately, store sample at 4° C for up to 3 days or at -20° C for up to 6 months. Avoid repeated freezing and thawing.

Usage and Instrumentation

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application sheets

Storage and Stability:

Store the reagents at 2-8°C. Avoid direct sunlight.
The Kit is stable till the expiry date mentioned on the labels when stored properly

Precautions

1. The Kit is for *in vitro* diagnostic use only.
2. The procedural instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Do not mix and use different lots of reagents.
5. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
6. Reagents contain sodium azide as preservative. Avoid contact with skin and eyes, flush with copious amounts of water when disposing.

Limitations:

The Kit is for *in vitro* use on automated chemistry analyzers only.
Hemolysis samples may cause inconsistent results.
The test result from the Kit should not be used as the only basis for definite diagnosis.

Quality Control:

High-Q PCT control is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

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Semi Auto Analyzers Assay Procedure:
(Multi Point Calibration with 5 Calibrator Levels)

System Parameters:

Reaction Type (Mode)	**Fixed Time- Non Linear- Multi Standard-Spline**
Reaction Direction	**Increasing**
Wave Length	**630 nm (600-630 nms)**
Flow Cell Temp.	**37°C**
Delay Time	**60 Seconds**
Measuring Time	**120 Seconds**
Blank	**Distilled Water Blank**
Reagent Volume	**360 µl (R1) + 120 µl (R2)**
Sample Volume	**50 µl**
Calibrator Concentrations	**(On the Vials Lot Specific)**
Linearity	**60 ng/mL**

Procedure :

Reagent	Calibrator	Serum/Control
R1	360 µl	360 µl
Calibrator	50 µl	----
Serum/Control	----	50 µl
Mix and incubate for 5 Minutes at 37 °C		
R2	120 µl	120 µl

1) Read absorbance A1 after 60 Seconds. (Delay)
2) Incubate and Read the absorbance A2 after 120 Seconds (Measuring)
3) Calculate the absorbance differences ΔA=A2–A1 for each point of the calibration curve, controls and all unknown samples.
4) The concentration of PCT in the unknown sample can be calculated from ΔA=A2–A1
5) Using a 3rd order polynomial mathematical model where abscissa (X) is the ΔA=A2–A1 and ordinate (Y) is the concentration of PCT or plotting the values of ΔA=A2–A1 obtained for every concentration level of the calibrator against the PCT concentration and interpolating the individual ΔA=A2–A1 of every sample in the calibration curve.

Calculations with Calibrators/ Calibration Curve/ Result Interpretation:

Calculation
The concentration of PCT in unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with 5 calibrators at deferent levels.
Stability of calibration: 4 weeks

Performance Characteristics:

Linearity: 0.05-60 ng/mL ($R^2 \geq 0.990$)

Accuracy: Relative deviation ≤15 %

Precision: Within Run: CV≤10%;
Run-to-Run: CV≤10%

Interference: no interference detected for: Triglyceride (1000 mg/dL), Ascorbic Acid (10mM), Hemoglobin (400 mg/dL), billirubin (40 mg/dL), and RF (200 IU/mL)

Expected Values:

Less than 0.5 ng/mL
It is recommended that each laboratory should establish it's own expected range

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 possible.

≥ 0.5 ng/mL and < 2 ng/mL:
Systemic infection is possible, but other non bacterial conditions are known to increase as well. Should be clinically correlated before starting the 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.

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 by non-

bacterial causes. These include, but are not limited to:

- **neonates < 48 hours of life (physiological elevation)**
- **the first days aaer a major trauma, major surgical intervenient severe burns, treatment with OKT3 antibodies and other drugs stimulate 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.

uch low levels may be obtained, during the early course of infections, in alized infections and in subacute endocarditis. Therefore, follow-up and evaluation of PCT in clinical suspicion of infection is pivotal. The PCT asuring technique should be chosen according to clinical use.

ny clinical diagnosis based on the test result must be supported by a comprehensive dgment of the concerned physician including clinical symptoms and other relevant t est results.

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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 condition increased PCT levels can be observed 3-6 hours afer an infectious challenge.

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

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.

ACCP: American College of Chest Physicians
SCCM: Society of Critical Care Medicine

[REFERENCES]

1. Müller B, *et al* ., Ubiquitous expression of the calcitonin -i gene in multiple i ssues in response to sepsis. *J ClinEndocrinolMetab 2001; 86(1):396-404.*
2. Meisner M. Procalcitonin (PCT) – A new, innovati e inffecti parameter. Biochemical and clin ical aspects. Thieme; *Stuttgrt, New York,* 2000; ISBN 3-13-105503-0.
3. Christ-Crain M, *et al*., Procalcitonin in bacterial infection – hype, hope or more or less? *Swiss Med Wkly* 2005; 135: 451-60.

High-Q Procalcitonin

Product Features

- **Latex Enhanced Turbidimetric Immuno Assay(LETIA)**
- **Liquid Stable Two Reagents**
- **5 Level Calibrator Set provided**
- **Measurement at 630 nms (600-630 nms)**
- **Test Procedure time 8 minutes at 37°C**
- **Linearity : 60.0 ng/mL**
- **Adaptable to Semi and Automated Analyzers**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C–8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

Manufactured by :-
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