

TurbiMAX Procalcitonin (PCT)

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

ORDERING INFORMATION

| Ref. No. | Pack Size | Presentation (R1 / R2 / Cal) |
|----------|-----------|-----------------------------------|
| AVPCT-20 | 20 ml | 1 x 15 ml / 1 x 5 ml / 5 x 0.5 ml |

INTENDED USE

TurbiMAX Procalcitonin (PCT) is an in-vitro diagnostic kit for the quantitative determination of PCT in human serum, EDTA or lithium heparin plasma. This kit is a automated.

INTENDED USER:

Laboratory Technician

PRODUCT FEATURES

1. Latex Enhanced Immunoturbidimetric Assay
2. Liquid Stable Two Reagents
3. 5 Level Calibrator Set provided
4. Measurement at 630 nms (600-630 nms)
5. Test Procedure time 8 minutes at 37°C
6. Linearity : 60.0 ng/mL
7. Adaptable to Semi and Automated Analyzers

CLINICAL SIGNIFICANCE:

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 process of the prohormone PCT, PCT is ubiquitously and uniformly expressed in multiple tissues throughout the body in response to sepsis¹. In healthy conditions, the PCT levels in circulation are very low (< 0.05 ng/ml). Elevated circulating levels of PCT are important indicators in response to microbial infections and a powerful tool in the early detection of sepsis²⁻⁸. Elevated PCT may not always be caused by systemic bacterial infection². If there is a disagreement between the laboratory findings and the clinical signs, additional tests should be performed.

PRINCIPLE

LiquiMAX Procalcitonin Assay is based on a latex enhanced immunoturbidimetry assay. PCT proteins in the sample bind to the specific anti-PCT antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of PCT in the sample. The instrument calculates the PCT concentration of a sample by interpolation of the obtained signal of a 6-point calibration curve.

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.

KIT COMPONENTS

1. PCT Reagent R1
2. PCT Reagent R2
3. PCT Calibrators (5) : Concentration as stated on the label

COMPOSITION

| | | |
|----|--|-----------|
| R1 | Tris Buffer Solution ---- | 0.2 mol/L |
| | NaCl ---- | 6.0 g/L |
| | PEG-6000 ---- | 22.0 g/L |
| R2 | Suspension of anti-human PCT monoclonal antibody coated latex Particles ---- | 0.3% |
| | BSA ---- | 3.0 g/L |
| | Tween-20 ---- | 3.0 ml/L |

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution. When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard reagent if blank reagent absorbance exceeds 1.4 at 630 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

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 upto 6 months. Avoid repeated freezing and thawing.

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 | Printed on the Vials Labels |
| Linearity | 60 ng/mL |

TEST PROCEDURE

| Reagent | Calibrator | Serum/Plasma |
|---|------------|--------------|
| R1 | 360 µl | 360 µl |
| Calibrator | 50 µl | ----- |
| Sample/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 $\Delta A = A2 - A1$ 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 $\Delta A = A2 - A1$
- 5 Using a 3rd order polynomial mathematical model where abscissa (X) is the $\Delta A = A2 - A1$ and ordinate (Y) is the concentration of PCT or plotting the values of $\Delta A = A2 - A1$ obtained for every concentration level of the calibrator against the PCT concentration and interpolating the individual $\Delta A = A2 - A1$ of every sample in the calibration curve. Calculation 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 different levels.

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 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 the antibiotic treatment.

PCT ≥ 2.0 ng/mL and < 10 ng/mL:

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

PCT ≥ 10 ng/mL

Important Systemic inflammatory response, due to severe bacterial or septic shock.

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 septicocoon increased PCT levels can be observed 3-6 hours after an infectious challenge. PCT levels are usually low in viral infections chronic inflamma- --tory disorders or autoimmune 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 cl conditions and a severe bacterial infection(sepsis)

Definitions

Definition for the terms of "SIRS", "SEPSIS", "Sever Sepsis" or "Septic shock" have been proposed by the ACCP/SCCM consensus Conference in 1992 and are now widely used see table below:

SIRS and sepsis definition

| | |
|--|---|
| (ACCP/SCCM-criteria) SIRS (Systemic Inflammatory Response Syndrome) | <ul style="list-style-type: none"> • Temperature > 38°C or < 36°C • Heart rate > 90 beats/min • Respiratory rate > 20 breaths/min or PaCO₂ < 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 inotropics or vasopressor agents may not be hypotensive at the time when perfusion Abnormalities are detected. |

QUALITY CONTROL & CALIBRATION:

Avecon's 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.

Stability of calibration: 4 weeks

PERFORMANCE CHARACTERESTICS:

1. Linearity

Linearity : 0.05-60 ng/mL (R²≥0.990)

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 0.05 ng/mL

3. Interferences:

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

4. Precision:

Intra-Assay

| N=20 | Mean (ng/mL) | SD (ng/mL) | CV% |
|-----------------|--------------|------------|------|
| Control serum 1 | 10.2 | 0.4 | 3.94 |
| Control serum 2 | 25.6 | 0.8 | 3.12 |
| Control serum 3 | 40.7 | 1.3 | 3.19 |

Inter-Assay

| N=20 | Mean (ng/mL) | SD (ng/mL) | CV% |
|-----------------|--------------|------------|------|
| Control serum 1 | 10.22 | 0.41 | 4.01 |
| Control serum 2 | 25.7 | 0.82 | 3.19 |
| Control serum 3 | 40.9 | 1.4 | 3.42 |

5. Method Comparison:

Results obtained using this reagent (y) were compared to those obtained with a Bayer immunoturbidimetric method. 39 samples ranging from 10 to 50 ng/mL of PCT were assayed. The correlation coefficient (r) was 0.92 and the regression equation y = 1.18 x - 37.8.

LIMITATIONS

0.05-60 ng/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in saline (10 parts serum sample + 40 parts normal saline ex: 10μl serum sample+40 μl saline) and retested again and the results should be multiplied by 5. The linearity limit and measurement range depends on the sample to reagent/ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.














WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES

1. Müller B, *et al.*, Ubiquitous expression of the calcitonin -i gene in multi le issues in response to sepsis. *J ClinEndocrinolMetab* 2001; 86(1):396-404.
2. Meisner M. Procalcitonin (PCT) – A new, innovative infec parameter. Biochemical and clinical aspects. Thieme; *Stuttgart, 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

Symbols Used on Pack

| | | | |
|---|---------------------------------|---|----------------------------------|
|  REF | Catalogue Number |  | Warning/Caution |
|  LOT | Batch No. |  | In vitro diagnostic device |
|  | Manufacturing Date |  | Storage Limit |
|  | Expiry Date |  | Consult instruction for use |
|  | Manufacturer |  | Keep away from sunlight |
|  | Keep Dry |  | Do not use if package is damaged |
|  | Contains sufficient no. of test | | |



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