PROCALCITONIN

(Turbilatex Method)

Intended Use

Procalcitonin is a reagent kit used for the quantitative determination of procalcitonin (PCT) in human serum. The reagents are for *in-vitro* diagnostic use.

Principle

Procalcitonin (PCT) in the test sample reacts with special antibody in the assay reagents, forming undissolved compounds and turbidity in the reaction solution. When the quantity of antibody is fixed, the resulting turbidity is determined by the concentration of Procalcitonin (PCT) in the sample at the test wavelength.

Reagent provided

1. R1 – PCT Buffer
2. R2 – PCT Antibody
3. R3 – Calibrator

Reagent storage and stability

The reagent and calbrator are stable till the expiry date stated on the container label.

Specimen collection and preservation

For specimen collection and preparation, only use suitable tubes or collection containers. Serum samples on an empty stomach are the recommended specimens. Collect fresh serum using standard sampling tubes. When processing samples in primary tubes, follow the instructions of the tube manufacturer. For samples with Absorbance interference, including samples of hemolysis and turbidity, may affect the test results. Sample recollection is recommended. Handle and test the sample immediately once after collection. If cannot test in time, then store serum less than 48 hours at 2-8°C, 1 month at -20° to -15°C. Protected from light and avoid repeated freeze thaw cycles.

Serial Dilutiion Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dilution	Neat	1/2	1/4	1/8	1/16

Assay guidelines for Analyzers

Reaction type	Fixed Point
Reaction slope	Increasing
Incubation time	3 mins
Wavelength	600 nm
Blank absorbance limit	A≤1.6
Sample volume	20 µl (0.020 ml)
Reagent volume	240 µl (0.240 ml)
Std. concentration	Refer Calibrator Vial
Low Normal	0.2 ng/ml
High Normal	50 ng/ml
Linearity	Up to 50 ng/mL

Assay guidelines for Manual procedure

Reagents	Calibrator (C)	Test (T)
R1 PCT Buffer	750 µl	750 µl
Calibrator	80 µl	-
Sample	-	80 µl
Mix well and incubate for 5 mins at 37°C		

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R2 PCT Antibody	250 µl	250 µl

Mix well, after about 120 sec at 37°C. Read the absorbance A1 of the test (T) and calibrator (C) gainst air or water. After exactly 300 secs (for all temperature), read the absorbance A2 of the test (T) and calibrator (C). Calculate ΔA/min. (A2-A1) for the test and calibrator.

Calculation

$$\text{PCT. Con.} = \frac{\Delta A\ (\text{Test})}{\Delta A\ (\text{Cal.})} \times \text{Calibrator Con.}$$

Normal Range

- PCT<0.5 ng/ml, recommending not to use antibiotic
- 0.5 ng/ml ≤ PCT < 1.0 ng/ml, suspected to be mild local bacterial infection or early stage of bacterial infection, or Viral infection, autoimmune disease, chronic nonspecific inflammation, suggest using antibiotic for emergency.
- 1.0 ng/ml ≤ PCT < 2.0 ng/ml, very possible to be general bacterial infection, unless it is one of the clinical status such as baby born in 48 hours, serious trauma, Burns, major surgery, and severe cardiac shock.
- 2.0 ng/ml ≤ PCT < 10 ng/ml, general bacterial infection (Sepsis), and very possible to develop severe sepsis.
- 10 ng/ml ≤ PCT, severe sepsis or septic shock

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

The result is only for clinical reference and cannot be used alone as the basis for diagnosis or exclusion of cases. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.

References

1. Viallon A, Guyomarch S, Marjollet O, et al. Can emergency Physicians identify a high mortality subgroup of patients with sepsis: role of procalcitonin [J]Eur Emerg Med, 2008, 15(1):26-33
2. Kyung-Eun Kim, M.D. And Jin-Yeong Han, M.d., Evaluation of the Clinical Performance of an Automated Procalcitonin Assay for the Quantitative.

Symbols

IVD In Vitro Diagnostics. Caution. Keep away from sun light. Date of Manufacture.

LOT Batch No. Read Instructions. Fragile. Product Expiry Date.

CONT Content. Storage Temperature. Keep Dry. Manufactured By.

REF Catalogue No.

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