TURBICHEM- PROCALCITONIN
(Latex Immunoturbidimetric)

KIT CONTENTS	PACK SIZE	CAT NO
TURBICHEM-PCT	1 x 40ML	TPCT01040M

GENUINE BIOSYSTEM

INTENDED USE
In vitro test for the quantitative determination of procalcitonin (PCT) in human serum.

SUMMARY AND EXPLANATION
Procalcitonin (PCT) comes from the single copy gene locating on the No. 11 chromosome (11p15,4). The gene consists of 280 base pairs, including 6 exons and 5 introns.

Procalcitonin (PCT) is an important inflammatory mark that reflects general infection. PCT test supplies meaningful reference information for the diagnosis, treatment and prognosis assessment of clinical infectious diseases, and reasonable use of antimicrobial agents[1].

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.

COMPONENTS

R1 – PCT Buffer	1 x 30ml
R2 – PCT Antibody	1 x 10ml
R3 – Calibrator	1 vial

STORAGE AND STABILITY
Stable for 18 months at 2 ～ 8℃, unopened and protect from light.

CONCENTRATION IN THE TEST
R1: Glycine Buffer
R2: Latex coated PCT-human Antibody

SPECIMEN COLLECTION AND HANDLING
Only the specimens listed below were tested and found acceptable.

For specimen collection and preparation, only use suitable tubes or collection containers.

Specimen: Serum samples on an empty stomach are the recommended specimens.

Serum: 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.

Stability: Handle and test the sample immediately once after collection. If cannot test in time, then store serum less than 48 hours at 2～8℃, 1 month at -20℃～-15℃. Protected from light and avoid repeated freeze thaw cycles.

PLOTTING OF MULTIPOINT CURVE
The Turbichem PCT is based on Non-Linear Reactions, hence it is strongly recommended to run multi-standard mode to plot the Multi-Point curve to have better accuracy and precise result.

Serial Dilution 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 Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE
These Reagents may be used for both manual assay sample start and in several automated analyzers. Application for them available on request.

WAVE LENGTH 600 nm
TEMPERATURE 37°C
CUVETTE 1CM

Reagent	Calibrator (C)	Test(T)
R1 – PCT Buffer	750 µl	750 µl
Calibrator	80 µl	
Sample		80 µl
Bring up to the room temperature of determination. Then add		
R2 – PCT Antibody	250 µl	250 µl

Mix well, after about 120 sec (37°C) read the absorbance A1 of the test (T) and calibrator© against 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.

CALICULATION
PCT concentration = ΔA (T)/ ΔA(C) x calibrator concentration

QUALITY CONTROL
1. Use matching control for daily quality control.
2. Values obtained should fall within the specified range. If not, please find the reason as following direction:
3. Check the parameter setting and light source
4. Check if the colorimetric cup and sampling needle is clear
5. Check if the water is contaminated, bacterial growth could cause incorrect result.
6. Check the reacting temperature
7. Check the validity period of the reagents
8. Calculate the difference of the calibrator's absorbance (A2-A1), and build the working curve of calibrator absorbance and concentration. Calculate the difference of the sample's absorbance, and get according concentration on the working line (ng/ml）

REFERENCE RANGE
1. PCT <0.5 ng/ml, recommending not to use antibiotic [2]

2. 0.5ng/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

3. 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.

4. 2.0 ng/ml ≦ PCT<10ng/ml, general bacterial infection (sepsis), and very possible to develop to severe sepsis.

5. 10ng/ml ≦ PCT,severe sepsis or septic shock.

Because of the differences in geography, race, and age, it is suggested that each hospital build its own reference range.

EXPLANATION OF TESTING RESULT

The result could be affected by age, sex, location of the subject. Normally, if the result falls within the reference range, it's considered normal; if it falls into the critical zone, re-test should be conducted; if it obviously exceeds the reference range or still exceed the range after re-test, the content of PCT in serum is considered abnormal. If the result is not consistent with the clinical situation, analyse and find the reason.

LIMITATIONS AND INTERFERENCE

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.

PERFORMANCE CHARACTERISTICS

The following performance data was obtained using analyser at 37°C. Results obtained in individual laboratories may differ.

Blank Absorbance: A ≤1.6

Linearity: 0.2ng/mL to 50 ng/mL

Accuracy: ≦15%

Precision: ≦15%

Analytical sensitivity: 0.1~0.4 at 15.0 ng/mL

Specificity analysis: hemoglobin≦400mg/dL, Triglycerides≦ 1000mg/dL, bilirubin≦40mg/dL, Vc≦100mg/dL, have no effect to testing value.

PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use.

2. Avoid skin and eye contact. Avoid ingestion.

3. Disposal of the used material in accordance with local guidelines. Avoid pollution and reuse.

4. Do not use the product if interior package is damaged during shipment.

5. The possibility of reagent instability or deterioration may be considered if there is precipitation, visible exudate, turbidity, microorganism growth, calibration results do not meet the appropriate standard specification, or control values out of range.

6. Exercise the normal precautions required for handling all laboratory reagents.

7. Wear protective clothing and disposable gloves while handling the kit reagents.
   a. Wash hands thoroughly after performing the test.
   b. Use in ventilated area.

For acids, include appropriate warnings for spills such as "wipe up spills immediately and flush with water" and "should the reagent contact eyes or skin, flush with copious amounts of water and consult a physician".

8. For biological spills, indicate appropriate disinfectants and disinfection procedure.

9. Dispose of all specimens and components of the kit as potentially infectious agents.

10. Do not use the kit or any kit component past the indicated expiry date.

11. Do not use any other reagents from different lots in this test, unless the reagent is designated to be used with other lots of the same kit. Avoid microbial contamination of reagents.

12. The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

BIBLIOGRAPHY

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

SYSTEM PARAMETERS

Method	Fixed Point
Wave Length	600 nm
Temperature setting	37°C
Incubation Temperature	37°C
Delay time	120 secs
Read Time	300 secs
Reaction Slope	Increasing
Sample Volume	80 µl
Reagent Volume	1000 µl
Standard Concentration	Refer Calibrator vial
Units	ng/mL
Linearity	50 ng/mL

IVD CE

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