

Procalcitonin Assay Kit (PCT)

Method: Latex Immunoturbidimetric

| Cat.NO. | Size | Instrument |
|---------|----------------------------|--|
| GS8671M | R1:1×45 ml R2:1×15 ml | For Hitachi917& OlympusAU640/400/600 |
| GK8671M | R1:1×45 ml R2:1×15 ml | For GCELL 9800 |
| GB8670M | R1:1×45 ml R2:1×15 ml | For Hitachi717&7150 ShimadzuCL7200/8000 |
| GM867M | R1:1×45 ml R2:1×15 ml | For GCELL 92000 |
| GH8671M | R1:1×45 ml R2:1×15 ml | For Hitachi 902 |
| GT8671M | R1:1×45 ml R2:1×15 ml | For TOSHIBA |
| GX8671M | R1:1×45 ml R2:1×15 ml | For SYNCHRON CX4-5- 7-9/LX20/DXC600-800 |
| GD8671M | R1:12×3.8ml R2:6×2.6 ml | For DATE DEMENSION |
| GC-PCT | | 5×1 ml |
| GQ-PCT | | 2×3 ml |

INTENDED USE

For the quantitative in vitro determination of Procalcitonin in serum and plasma.

CLINICAL SIGNIFICANCE

PCT is a parameter to diagnose and monitor inflammatory diseases of bacterial infections. Determination of PCT can indicate the following Information: ① As a parameter to diagnose acute bacterial & non-bacterial infections and inflammation. ② Monitor the patients who are at high risk of infection period (such as after surgical postoperative and immunosuppression period after organ transplantation, multiple trauma) and intensive care patients, to detect bacterial infection or to detect septic complications. ③ Evaluate the clinical course and prognosis of severe inflammatory disease [1].

ASSAY PRINCIPLE

Procalcitonin is reacted with latex particles coated with anti-PCT antibody, generate agglutination reaction, then detect the absorbance at a wavelength of 600nm, with the magnitude change being related to the quantity of PCT in the sample.

REAGENT COMPOSITON

| Contents | Concentration of Solutions |
|--|----------------------------|
| Reagent 1 (R1) | |
| Tris buffer | 100mmol/L |
| Reagent 2 (R2) | |
| Latex particles coated with monoclonal mouse anti-PCT antibody | 0.2% |

SAMPLE COLLECTION AND PREPARATION

Fresh Serum, heparinized plasma or EDTA plasma samples can be used for the assay.

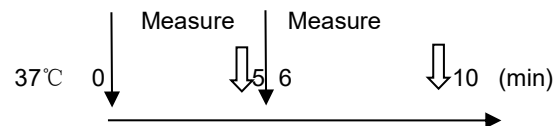
STABILITY AND PREPARATION OF REAGENTS

The reagents should be stored at 2-8° C. Do not freeze. The reagents and controls are stable when stored as instructed until the expiration date on the label.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi7180)
Assay Mode: 2 Point End 18-28
Wave length (main): 600nm

Sample 15 µl
R1: 180µl R2: 60 µl



CALIBRATION

Recommend using Gcell PCT Calibrator(Cat No.: GC-PCT) which contained inside the kit.

CALCULATION OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{\text{sample}} / \text{min}}{\Delta A_{\text{calibrator}} / \text{min}} \times \text{Calibrator value}$$

QUALITY CONTROL

For quality control, use Gcell PCT Control (GQ-PCT) as daily quality control sera. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

REFERENCE RANGE

<0.5ng/mL

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

PERFORMANCE CHARACTERISTICS

PRECISION

The coefficient of variation (CV) for both Intra assay precision and Inter assay precision is below 10%

| Intra assay precision | | |
|-----------------------|----------|----------|
| N=20 | Sample 1 | Sample 2 |
| Mean(ng/ml) | 0.77 | 5.93. |
| SD | 0.03 | 0.07 |
| CV(%) | 3.9 | 1.19 |

| Inter assay precision | | | |
|-----------------------------|---------|---------|---------|
| N=5 | Batch 1 | Batch 2 | Batch 3 |
| Mean(ng/ml) | 0.79 | 0.75 | 0.76 |
| \bar{x} | 0.77 | | |
| $(X_{max}-X_{min})/\bar{x}$ | 5.19% | | |

LINEARITY

The method is linear up to 50 ng/ml. If the samples above this concentration should be diluted 1:1 with 0.9% NaCl and repeat assay. Multiply the result by 2.

INTERFERENCE

The following analytes were tested up to levels indicated and found not to interfere:

| | |
|----------------|-----------|
| Ascorbic acid: | 10 mM |
| Bilirubin: | 40 mg/dL |
| Hemoglobin: | 200 mg/dL |
| Triglycerides: | 270 mg/dL |
| RF: | 75 IU/mL |

CORRELATION

Tested the serum samples with Gcell PCT assay kit and a well-known brand kit at the same time. The correlation formula is $y=0.93x+0.227$ $R^2=0.984$

SENSITIVITY

Compared the absorbance of a certain concentration and the water. When the concentration is 0.3 ng/mL,

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Dingning. The expert consensus of procalcitonin (PCT) in emergency clinical application [J]. Chin J Emerg Med, September 2012, Vol 21, No.944-848

2. Diazyme. Procalcitonin, a specific marker for diagnosis of bacterial infection and sepsis.

INDEX OF SYMBOLS



Manufacture



Catalogue Number



Lot number



Date of manufacture



Use by (Expiration date)



For In-Vitro Diagnostic use only



Stored at 2-8°C



Attention: See instruction for use



Authorized Representative in the European Company