PCT

Procalcitonin (FIA)

infinosis™

REF: IN057701 Σ 25

Intended use
The infinosis™ PCT is a fluorescence immunoassay for the in vitro quantitative determination of procalcitonin (PCT) in Human whole blood, serum, or plasma. For professional use only.

Summary
References[1-11]
Procalcitonin (PCT) is a 116 amino acid prohormone with a molecular weight of approximately 12.7 kD. PCT is expressed by neuroendocrine cells (C cells of the thyroid, pulmonary and pancreatic tissues) and successively enzymatically cleaved into (immature) calcitonin, katacalcin, and an N−terminal region. The blood of healthy individuals contains only low levels of PCT. It was discovered that PCT increases during bacterial infection. It is probable that multiple tissues express PCT throughout the body in 3 response to sepsis as was shown in an animal model. PCT circulating in septic patients consists of only 114 amino acids lacking the N-terminal dipeptide Ala-Pro. Increased PCT levels are often found in patients suffering from bacterial sepsis, especially severe sepsis and septic shock. PCT is considered as a prognostic marker to support outcome prediction in sepsis patients.
In acute pancreatitis PCT was found to be a reliable indicator of severity and of major complications. In patients suffering from community-acquired respiratory tract infections or ventilator−induced pneumonia PCT has been proposed as a guide for the decision of antibiotic treatment necessity and to monitor treatment success.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-PCT antibody binds to PCT antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and PCT are captured to anti-PCT antibody that has been immobilized on test strip. Thus the more PCT antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of PCT captured and instrument for infinosis™ tests shows PCT concentrations in blood specimen.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip**, 1 pcs
- **Sample Buffer,** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ 2020 FIA analyzer
- PCT control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ PCT should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ PCT assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report
Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability
- Store the test kit at 2-30℃, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either serum or plasma or whole blood.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 ℃) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests and read ID chip information.
2. Using a pipette to transfer **50 µL** of sample (Human whole blood/plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.

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10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference
- The false positive results include cross-reactions with some components of serum from individual to antibodies; and non-specific adhesion of some components in human blood that have similar epitopes to capture and detector antibodies.
- In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of PCT antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
- Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in Infinosis™ PCT assay and thus should not be used.
- Other factors may interfere with Infinosis™ PCT assay and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range
0.05-100 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 0.05 ng/mL. Values above the measuring range are reported as > 100 ng/mL.

Lower detection limit
0.05 ng/mL
The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 21).

Expected values
A study performed with Infinosis™ PCT assay using 272 samples from apparently healthy males (137) and females (135) revealed the following normal value: 0.05 ng/mL (95th percentile).

Clinical cut-off
Results obtained with the Infinosis™ PCT assay are in agreement with the literature. A study performed on samples from patients admitted to an ICU (intensive care unit) showed that PCT values:
< 0.5 ng/mL represent a low risk of severe sepsis and/or septic shock
> 2.0 ng/mL represent a high risk of severe sepsis and/or septic shock
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data
Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision
Intra-assay
Determined by by using 10 replicates of specimen 80 ng/mL PCT, CV ≤ 15%

Inter-assay
Determined by using 3 replicates for each of three lots using PCT specimen levels at 80 ng/mL, CV ≤ 15%.

Linearity
A serial concentration of PCT controls at 0.5 ng/mL, 2.0 ng/mL, 10 ng/mL, 20 ng/mL, 50 ng/mL, and 80 ng/mL were each tested for three times, the Correlation Coefficient is: r ≥ 0.9964

Method comparison
A comparison of the infinosis™ PCT assay (y) with the Roche BRAHMS PCT assay (x) using 117 clinical samples gave the correlation: r=0.9556

Functional sensitivity
0.08 ng/mL
The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

References

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Symbols

IVD In vitro diagnostic medical device	Temperature limit	Consult instructions for use	REF Catalog number
LOT Batch code	Date of manufacture	Use-by date	Contains sufficient for <n> tests
Manufacturer	Do not re-use	Do not use if package is damaged and consult instructions for use	
CE European Conformity	EC REP Authorized representative in the European Community		

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