# QDx Instacheck™ PCT

## INTENDED USE

**QDx Instacheck™ PCT** in conjunction with the **QDx Instacheck™ Reader** is a fluorescence immunoassay for quantitative measurement of procalcitonin (PCT) concentration in human whole blood/serum/plasma for diagnosis of bacterial infection and sepsis.

## INTRODUCTION

Sepsis is a daily challenge in intensive care units. Today various therapeutic strategies are known to improve survival in patients with sepsis. Early assessment is important for determination of the appropriate treatment.

In healthy people, plasma PCT concentrations are found to be below 0.1 ng/mL. PCT levels rise rapidly (within 6 – 12 hours) after a bacterial infectious insult with systemic consequences. Early after situations like multiple traumas, major surgery, severe burns, or in neonates, PCT levels can be elevated independently of an infectious process, but the return to baseline is usually rapid. Viral infections, bacterial colonization, localized infections, allergic disorders, autoimmune diseases, and transplant rejection do not usually induce a significant PCT response (values < 0.5 ng/mL). Therefore, by evaluating PCT concentrations, the physician may use the findings to aid in the risk assessment for progression to severe sepsis and septic shock.

## PRINCIPLE

The test uses a sandwich immunodetection method, such that the detector antibody in buffer binds to PCT in serum sample and antigen-antibody complexes are captured to another PCT antibody that has been immobilized on test strip as sample mixture migrates nitrocelluose matrix. Thus the more PCT antigen in serum, the more antigen-antibody complexes accumulated on the test strip. Signal intensity of fluorescence on detector antibody reflects the amount of antigen captured and is processed by **QDx Instacheck™ Reader** to show PCT concentration in specimen.

## COMPONENTS AND REAGENTS

**QDx Instacheck™ PCT** consists of a 'Cartridge', an 'ID Chip', and a 'Detection Buffer Tube'.

- The test cartridge contains a test strip; on the membrane of which, Anti-PCT antibody and chicken IgY have been immobilized at the test line and the control line respectively.
- Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 10 sealed test cartridges are packed in a box which also contains an ID chip.
- The detection buffer pre-dispensed in a tube contains fluorochrome-labeled anti-PCT antibodies, fluorescent-labeled anti chicken IgY, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is dispensed in each detection buffer tube. 10 detection buffer tubes are packed in a separate box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, ID chip and detection buffer) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test result(s).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- **QDx Instacheck™ PCT** as well as the **QDx Instacheck™ Reader** should be used away from vibration and/or magnetic field. During normal usage, it can be noted that **QDx Instacheck™ Reader** may produce minor vibration.
- Used detection buffer tubes, pipette tips and cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **QDx Instacheck™ PCT** will provide accurate and reliable results subject to the following conditions.
  - **QDx Instacheck™ PCT** should be used only in conjunction with **QDx Instacheck™ Reader**.
  - Any anticoagulants other than **EDTA, heparin, citrate** should be avoided.

## STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in the aluminum foil pouch) if stored at 4-30 °C.
- The detection buffer dispensed in the detection buffer tube is stable for 20 months if stored at 2-8 °C.
- After the cartridge pouch is opened, the test should be performed immediately.

## LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

## SAMPLE COLLECTION AND PROCESSING

The sample type for **QDx Instacheck™ PCT** is human whole blood/serum/plasma.

- It is recommended to test the sample within 24 hours after

collection

- Take precautions on the collected sample because it's reported the concentration is rapidly changed when the sample for PCT test is kept at room temperature or refrigerated.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20 °C. The freezing storage of sample up to 3 months does not affect the quality of results.
- Do not freeze whole blood sample in any case.
- Once the sample was frozen, it should be thawed one time and only for test, because repeated freezing and thawing can result in the changed test values.

## MATERIALS SUPPLIED

**REF IFPC-10-1**

**Components of QDx Instacheck™ PCT**

- **Cartridge Box:**
  - Cartridges 10
  - ID Chip 1
  - Instruction For Use 1
- **Box containing Detection Buffer Tube:**
  - Detection Buffer Tubes 10

## MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ PCT**. Please contact our sales division for more information.

- **QDx Instacheck™ Reader** REF FPRR010
- Thermal Printer

## TEST SETUP

1. Check the components of **QDx Instacheck™ PCT**: Sealed Test Cartridge, ID Chip, and Detection Buffer Tube.
2. Ensure that the lot number of the test cartridge matches with that of the ID chip as well as the detection buffer tube.
3. Keep the sealed test cartridge (if stored in refrigerator) and the detection buffer tube at room temperature for at least 30 minutes just prior to the test. Place the test cartridge on a clean, dust-free and flat surface.
4. Turn on the **QDx Instacheck™ Reader**.
5. Insert the ID chip into the 'ID Chip Port' of the **QDx Instacheck™ Reader**.
6. Press 'Select' button on the **QDx Instacheck™ Reader**. (*Please refer to the '**QDx Instacheck™ Reader** Operation Manual' for complete information and operating instructions*.)

## TEST PROCEDURE

[Single mode]

1. Transfer 150 µL of the human whole blood/serum/plasma/control sample using a transfer pipette to the tube containing the detection buffer**.**
2. Close the lid of the detection buffer tube and mix the sample thoroughly with the detection buffer by shaking the tube about 10 times.
3. Pipette out 75 µL of this sample mixture from the detection buffer tube and dispense it into the sample well on the test cartridge.
4. For scanning the sample-loaded test cartridge, insert it into the test cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
5. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
6. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge after 12 minutes.
7. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

[Multi mode]

1. Transfer 150 µL of the human whole blood/serum/plasma/control sample using a transfer pipette to the tube containing the detection buffer.
2. Close the lid of the detection buffer tube and mix the sample thoroughly with the detection buffer by shaking the tube about 10 times.
3. Pipette out 75 µL of this sample mixture from the detection buffer tube and dispense it into the sample well on the test cartridge.
4. Leave the sample-loaded test cartridge at room temperature for 12 minutes.
5. For scanning the sample-loaded test cartridge, insert it into the test cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
6. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
7. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge immediately.
8. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

## INTERPRETATION OF TEST RESULT

- **QDx Instacheck™ Reader** calculates the test result automatically and displays PCT concentration of the test sample in terms of ng/mL.
- Cut-off of **QDx Instacheck™ PCT** is 0.5 ng/mL.
  - **QDx Instacheck™ PCT** test should be considered as a screening tool only. In case of a positive result (above 0.5 ng/mL), consult a physician to discuss the test result. The physician may decide further course of action.
  - Test result of > 2 ng/mL may reflect severe sepsis.

| Diagnosis of bacterial infection/sepsis | |
|---|---|
| [ng/mL] | state |
| PCT<0.5 | Local bacterial infection is possible |
| 0.5<PCT<2 | Infection is possible |
| 2<PCT<10 | Infection (sepsis) is likely, unless other cause are known |
| PCT>10 | Severe bacterial sepsis or septic shock |

- Working range of **QDx Instacheck™ PCT** is 0.1-100 ng/mL.

## QUALITY CONTROL

- Quality control tests should be performed as a part of the good testing practice to confirm the expected quality control results and validity of the assay as well as to ensure accuracy of the test results with clinical samples.
- A quality control test should be performed at regular intervals. Before testing a clinical sample using a new test lot, control reagents should be tested to confirm the test procedure, and to verify whether the test produces the expected quality control

results. Quality control tests should also be performed whenever there is any question concerning the validity of the test results.

- Control standards are not provided with **QDx Instacheck™ PCT**. For more information regarding obtaining the control standards, contact the technical section at **Diasys Diagnostics India Private Limited**.
- **Internal Control**: **QDx Instacheck™ PCT** test has an in-built quality control indicator that satisfies the routine quality control requirements. This internal control test is performed automatically each time a clinical sample is tested. An invalid result from the internal control leads to display an error message on the **QDx Instacheck™ Reader** indicating that the test should be repeated.

## PERFORMANCE CHARACTERISTICS

**1. Analytical sensitivity**

| | | |
|---|---|---|
| Limit of Blank | (LoB) | 0.04 ng/mL |
| Limit of Detection | (LoD) | 0.06 ng/mL |
| Limit of Quantification | (LoQ) | 0.10 ng/mL |

**2. Analytical specificity**

- **Cross-reactivity**

There was no significant cross-reactivity from these materials with the **QDx Instacheck™ PCT** test measurements.

| Cross-reactivity material | Standard material conc. (ng/mL) | | |
|---|---|---|---|
| | 0.561 | 1.24 | 13.1 |
| | Recovery (%) | | |
| Pro-BNP (100 ng/mL) | 99 | 101 | 97 |
| Pro-GRP (100 ng/mL) | 99 | 99 | 97 |
| Pro-ANP (100 ng/mL) | 96 | 100 | 104 |

- Interference

There was no significant cross-reactivity from these materials with the **QDx Instacheck™ PCT** test measurements.

| Interference material | Standard material conc. (ng/mL) | | |
|---|---|---|---|
| | 0.561 | 1.24 | 13.1 |
| | Recovery (%) | | |
| Bilirubin (conjugated) (40 mg/mL) | 98 | 101 | 101 |
| Cholesterol (10 mM/dL) | 97 | 102 | 100 |
| D-Glucose (60 mM/L) | 96 | 99 | 100 |
| Hemoglobin (200 mg/dL) | 99 | 99 | 98 |
| L-Ascorbic acid (0.2 mM/L) | 96 | 99 | 100 |
| Triglyceride (10 mg/mL) | 97 | 98 | 97 |

**3. Precision**

- Between lot

One person tested three different lots of **QDx Instacheck™ PCT**, three times at each concentration of the control standard.

- Between person

Three different persons tested **QDx Instacheck ™ PCT**; three times at each concentration of the control standard.

- Between day

One person tested **QDx Instacheck ™ PCT** during five days; five times at each concentration of the control standard.

- Between site

One person tested **QDx Instacheck ™ PCT** at three different sites; five times at each concentration of the control standard.

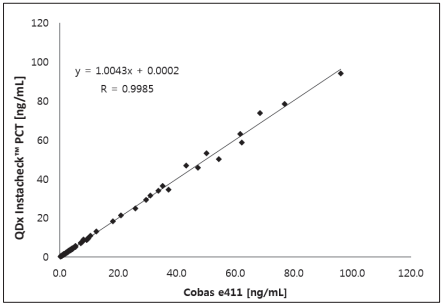
| conc. | Between-lot | | Between-person | | Between-day | | Between-site | |
|---|---|---|---|---|---|---|---|---|
| [ng/mL] | AVG | CV(%) | AVG | CV(%) | AVG | CV(%) | AVG | CV(%) |
| 0.468 | 0.46 | 6.9 | 0.45 | 7.2 | 0.47 | 3 | 0.47 | 3 |
| 1.07 | 1.05 | 6.7 | 1.08 | 6.0 | 1.08 | 1 | 1.07 | 0 |
| 10.8 | 10.73 | 7.3 | 10.63 | 6.8 | 10.91 | 2 | 10.77 | 4 |

**4. Accuracy**

The accuracy was confirmed by 3 different lots testing ten times each different concentrations.

| PCT [ng/mL] | Lot 1 | Lot 2 | Lot 3 | AVG | Recovery(%) |
|---|---|---|---|---|---|
| 0.468 | 0.47 | 0.46 | 0.47 | 0.46 | 99.3 |
| 1.07 | 1.06 | 1.08 | 1.06 | 1.07 | 100.0 |
| 10.8 | 10.59 | 10.65 | 10.62 | 10.62 | 98.3 |

**5. Comparability (Correlation):** Using Roche Cobas e411 as a comparison machine for **QDx Instacheck™ PCT**, 100 serum samples were independently tested for its PCT concentration following each instrument's procedure. Results of both the test methods were analyzed and their comparability was investigated with linear regression and coefficient of correlation (R). The coefficient of correlation between the two methods was found to be R =0.9985.

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**Note:** Please refer to the table below to identify various symbols.

| | |
|---|---|
| | Sufficient for <n> tests |
| | Read instruction for use |
| | Use by Date |
| LOT | Batch code |
| REF | Catalog number |
| | Caution |
| | Manufacturer |
| EC REP | Authorized representative of the European Community |
| IVD | In vitro diagnostic medical device |
| | Temperature limit |
| | Do not reuse |
| CE | This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices |

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