QDx Instacheck™ PCT Plus

INTENDED USE

QDx Instacheck™ PCT Plus is a fluorescence Immunoassay (FIA) for the quantitative determination of Procalcitonin (PCT) in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of bacterial infection and sepsis.
For in *vitro* diagnostic use only.

INTRODUCTION

Identifying sepsis is a daily challenge in intensive care unit of every hospital. Early assessment of sepsis is vital for determination of the appropriate treatment since various therapeutic strategies are known to improve survival of patients with sepsis.
In healthy people, the concentration of plasma PCT is below 0.1 ng/mL the level of PCT rises rapidly after a bacterial infection with systemic consequences. It can also be elevated by other situation such as major surgery, severe burns, or in neonates. However, it returns to baseline rapidly. 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 physicians are able to engage in the risk assessment for progression to severe sepsis and septic shock.

PRINCIPLE

The test uses a sandwich immunodetection method; Dried antibodies in the detector tube, once diluted with the diluent, bind with antigens in the sample to form antigen-antibody complexes. These complexes then migrate through the nitrocellulose matrix and are captured by other sets of immobilized antibodies on the test line.
The more antigens in the sample, the more antigen-antibody complexes, which leads to a stronger fluorescence signal. This signal then is interpreted by the reader to display the PCT concentration in the sample.

COMPONENTS AND REAGENTS

QDx Instacheck™ PCT Plus consists of 'Cartridges', 'Detectors', 'Diluent', 'Capillary tubes' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has streptavidin at the test line, with chicken IgY at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip and 25 sealed capillary tubes.
- The detector contains anti human PCT-fluorescence conjugate, anti-chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline (PBS).
- Each detector contains 2 granules. 25 tubes of detector are packed in a pouch and packed in a box with 5 ml of diluent.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- 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, detectors and diluent) 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 incorrect test result(s).
- Do not reuse cartridges or detector tubes. A detector tube should be used for processing of one sample only. A cartridge should be used for testing one sample only
- The cartridge should remain sealed in its original pouch until just before use. Do not use cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the local regulations. A sample with severe hemolysis and/or hyperlipidemia must not be used.
- Allow the cartridge, detector, diluent and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for QDx Instacheck™ tests may generate slight vibration during use.
- Used detectors, diluent, pipette tips, capillary tubes 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 Plus** will provide accurate and reliable results subject to the below conditions.
  - **QDx Instacheck™ PCT Plus** should be used only in conjunction with QDx Instacheck™ tests.
  - Have to use recommended anticoagulant sample.

Recommended anticoagulant
K2 EDTA, Sodium heparin, Sodium citrate

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	4 - 30 °C	24 months	Disposable
Detector	2 - 8 °C	24 months	
Diluent	2 - 8 °C	24 months	Unopened
	2 – 8 °C	12 months	opened

- 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.

MATERIALS SUPPLIED

REF IFPC-32

Components of **QDx Instacheck™ PCT Plus**

- **Cartridge Box:**
  - Cartridges 25
  - 35 µL Capillary tube 25
  - ID Chip 1
  - Instruction for Use 1
- **Buffer box:**
  - Detectors 25
  - Diluent 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

- **QDx Instacheck™ II** REF FPRR021
- **Boditech PCT Plus Control** REF CFPO-225

SAMPLE COLLECTION AND PROCESSING

The sample type for **QDx Instacheck™ PCT Plus** 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.

TEST SETUP

- Check the components of **QDx Instacheck™ PCT Plus**: Sealed Cartridge, Detectors, Diluent, Capillary tubes and ID Chip
- Ensure that the lot number of the test cartridge matches with that of the ID chip as well as the buffer box.
- Keep the sealed test cartridge (if stored in refrigerator) and the buffer box 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.
- Turn on the instrument for QDx Instacheck™ Test.
  (Please refer to the instrument 'QDx Instacheck™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

[Multi mode]

1. Transfer 150 µL of detector diluent using a pipette to a detector tube containing granules. When the granule form is completely dissolved in the tube, it becomes detection buffer. The detection buffer must be used immediately within 3 minutes.
2. Transfer 35 µL of sample (Human whole blood/ serum/ plasma/ control) to the detector tube.
   * If you use a capillary tube (35 µL), put it into the detector tube after collecting whole blood sample.
3. Close the lid of the detector tube and mix the sample thoroughly by shaking it about 20 times. The sample mixture must be used immediately within 3 minutes.
4. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for 12 minutes before inserting the device into the holder.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
6. To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for QDx Instacheck™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
7. Tap the 'START' button on the instrument for QDx Instacheck™ test to the start the scanning process.
8. Instrument for QDx Instacheck™ test will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for QDx Instacheck™ tests.

[Single mode]

1. Transfer 150 µL of detector diluent using a pipette to a detector tube containing granules. When the granule form is completely dissolved in the tube, it becomes detection buffer. The detection buffer must be used immediately within 3 minutes.
2. Transfer 35 µL of sample (Human whole blood/serum/plasma/ control) to the detector tube.
   * If you use a capillary tube (35 µL), put it into the detector tube after collecting whole blood sample.
3. Close the lid of the detector tube and mix the sample thoroughly by shaking it about 20 times. The sample mixture must be used immediately within 3 minutes.
4. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
5. To scan the sample-loaded test cartridge, insert it into the test cartridge holder of the QDx Instacheck™ tests. 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. Tap the 'START' button on the instrument for QDx Instacheck™ test to the start the scanning process.
7. Cartridge goes inside the Instrument for QDx Instacheck™ tests and will automatically start scanning the sample-loaded cartridge after 12 min.
8. Read the test result on the display screen of the QDx Instacheck™ tests.
   (Please refer to the QDx Instacheck™-II operation manual for complete information and operation instructions.)

INTERPRETATION OF TEST RESULT

- QDx Instacheck™ tests calculates the test result automatically and displays PCT concentration of the test sample in terms of ng/mL.
- Cut-off of (reference value): 0.5 ng/mL
  - **QDx Instacheck™ PCT Plus** 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 is known
PCT>10	Severe bacterial sepsis or septic shock

- Working range: 0.02-50 ng/mL

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 standards are not provided with **QDx Instacheck™ PCT Plus.** For more information regarding obtaining the control standards, contact the technical section at Diasys Diagnostics India Private Limited.
  (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical sensitivity**
  - Limit of Blank (LoB) 0.01 ng/mL
  - Limit of Detection (LoD) 0.02 ng/mL
  - Limit of Quantification (LoQ) 0.02 ng/mL

- **Analytical specificity**
  - Cross-reactivity
    Biomolecules such as below the ones in the table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **QDx Instacheck™ PCT Plus** test results did not show any significant cross-reactivity with these biomolecules measurements.

Cross-reactivity material	Conc. [ng/mL]
Pro-BNP	100
Pro-GRP	100
Pro-ANP	100

  - Interference
    Interference materials such as below the ones in the table were added to the test sample(s) the same as the below concentrations. **QDx Instacheck™ PCT Plus** test results did not show any significant interference with these materials.

Interference material	Conc.
Bilirubin (conjugated)	342 umol/L
Cholesterol	13 mmol/L
D-Glucose	55 mmol/L
Hemoglobin	2 g/L
L-Ascorbic acid	170 umol/L
Triglyceride	37 mmol/L
EDTA	3.4 µmol/L
Heparin	3,000 U/L
Citrate	2 mg/mL

- **Precision**
  - Between lot
    One person tested three different lots of **QDx Instacheck™ PCT Plus**, ten times at each concentration of the control standard.
  - Between person
    Three different persons tested **QDx Instacheck™ PCT**, ten times at each concentration of the control standard.
  - Between day
    One person tested **QDx Instacheck™ PCT Plus** for five days, ten times at each concentration of the control standard.
  - Between site
    Three persons tested **QDx Instacheck™ PCT Plus** at three different sites, ten times at each concentration of the control standard.

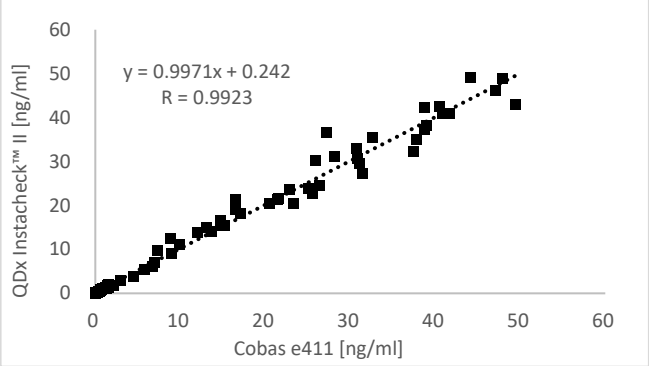
Conc. (ng/mL)	between Lot		between person		between day		between site	
	mean	CV (%)	mean	CV (%)	mean	CV (%)	mean	CV (%)
0.2	0.2	5.6	0.2	5.64	0.2	5.92	0.2	5.98
0.78	0.79	6.03	0.78	5.8	0.78	5.78	0.77	5.22
3.13	3.19	5.94	3.14	6.24	3.11	6.03	3.11	5.86

- **Accuracy**
  The accuracy was confirmed by 3 different lots testing ten times each different concentration.

PCT [ng/mL]	Lot 1	Lot 2	Lot 3	AVG	Recovery (%)
0.2	0.2	0.2	0.2	0.2	101%
0.78	0.75	0.8	0.77	0.77	99%
3.13	3.17	3.16	3.11	3.15	101%

- **Comparability (Correlation):**
  PCT concentration of 100 standard materials were quantified independently with **QDx Instacheck™ PCT Plus** and Cobas e411 (Roche Diagnostics Inc. Switzerland) as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests are as follows respectively.

Linear regression	coefficient of correlation (R)
y = 0.9971x + 0.242	0.9923



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

Σ	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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