BIO TECHNOLOGY boditech

Infection

ichroma™ PCT

INTENDED USE

ichroma™ PCT 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; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by instrument for ichroma™ tests to show PCT concentration in sample.

COMPONENTS

ichroma™ PCT consists of 'Cartridges', 'Detection Buffer Tubes' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human PCT at the test line, while 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.
- The detection buffer contains anti human PCT-fluorescence conjugate, anti human PCT-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packaged in a box and further packed in a Styrofoam box with ice-pack for the 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.
- **ichroma™ PCT** as well as the instrument for ichroma™ tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that instrument for ichroma™ tests 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.
- **ichroma™ PCT** will provide accurate and reliable results subject to the following conditions.
  - Use **ichroma™ PCT** should be used only in conjunction with instrument for ichroma™ tests.
  - Any anticoagulants other than **EDTA, heparin, citrate** should be avoided.

STORAGE AND STABILITY

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

LIMITATION 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 CFPC-23

Components of **ichroma™ PCT**

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

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FR203
  - **ichroma™ D** REF 13303
- **ichroma™ Printer** REF FPRR007
- **Boditech PCT Control** REF CFPO-97

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ 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.

TEST SETUP

- Check the contents of **ichroma™ PCT**: Sealed Cartridge, Detection Buffer Tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.
- Keep the sealed 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 cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for ichroma™ tests.
- Insert the ID Chip into the ID chip port of the instrument for ichroma™ tests**.**
- Press the 'Select' button on the instrument for ichroma™ tests. (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

1) Transfer 150 µL of the human whole blood/serum/plasma/ control sample using a transfer pipette to a tube containing the detection buffer**.**
2) Close the lid of the detection buffer tube and shake the 10 times or more until the sample out of the sample collector by inversion.
3) Pipette out 75 µL of sample mixture and load it into the sample well on the test cartridge.
4) Leave the sample-loaded cartridge at room temperature for 12 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
5) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ 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.
6) Press 'Select' button on the instrument for ichroma™ tests to start the scanning process.
7) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
8) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays PCT concentration of the test sample in terms of ng/mL.
- The cut-off (reference value): 0.5 ng/mL
  - **ichroma™ 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: 0.1-100 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 materials are not provided with **ichroma™ PCT**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance. (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **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

- **Analytical specificity**

- Cross reactivity

There was no significant cross-reactivity from these materials with the **ichroma™ 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 **ichroma™ 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

- **Precision**

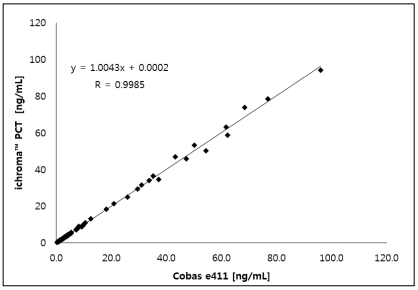
- Between lot
  One person tested three different lots of **ichroma™ PCT**, three times at each concentration of the control standard.
- Between person
  Three different persons tested **ichroma™ PCT**; three times at each concentration of the control standard.
- Between day
  One person tested **ichroma™ PCT** during five days; five times at each concentration of the control standard.
- Between site
  One person tested **ichroma™ 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	1.08	1	1.07	0
10.8	10.73	7.3	10.63	6.8	10.91	2	10.77	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

- **Comparability**
  Using Roche Cobas e411 as a comparison machine for **ichroma™ 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

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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