



ichroma™ PCT Plus

INTENDED USE

ichroma™ 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 another 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

ichroma™ 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) should agree.

- Do not interchange test components between different lots or use 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 the cartridge, if pouch is damaged or has already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. A Sample with severe hemolysis and/or hyperlipidemia must not be used.
- Allow the cartridge, the detector and the sample to be at a room temperature for approximately 30 minutes before use.
- The instrument for **ichroma™** tests may generate slight vibration during use.
- Used detectors, 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 Plus** will provide accurate and reliable results subject to the below conditions.
 - **ichroma™ PCT Plus** should be used only in conjunction with instrument for **ichroma™** tests.
 - Have to use recommended anticoagulant sample.

Sample type	Recommended anticoagulant
Whole blood	EDTA, heparin, citrate
Plasma	
Serum	Not applicable.

STORAGE AND STABILITY

- The cartridge is stable for 24 months (while sealed in the original aluminum foil pouch) if stored at 4-30 °C.
- The detector and the diluent are stable for 24 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(s) due to the non-responsiveness of the antigen to the antibodies which is most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also 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-64

- Components of **ichroma™ PCT Plus**
 - Cartridge Box:

- Cartridges	25
- 35 µL Capillary tube	25
- ID Chip	1
- Instruction For Use	1
■ Buffer Box	
✓ For ichroma™ II, ichroma™ 100	
- Detectors (Capped with plastic lid)	25
- Diluent	1
✓ For AFIAS-50	
- Detectors (Sealed with aluminum foil)	25
- Diluent	1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ PCT Plus**.

Please contact our sales division for more information.

- Instrument for ichroma™ tests
 - **ichroma™ II** REF FPRR021
 - **ichroma™ 100** REF FPRR029
 - **AFIAS-50** REF FPRR022
- **Boditech PCT Plus Control** REF CFPO-225

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ 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 only once and only for test, because repeated freezing and thawing can result in the changed test values.

TEST SETUP

- Check the contents of **ichroma™ PCT Plus**: Sealed Cartridge, Detectors, Diluent, Capillary tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the buffer box.
- Keep the sealed cartridge (if stored in refrigerator) and the buffer box 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

▶ **ichroma™ II, ichroma™ 100**

<Multi Mode>

- 1) Transfer 150 µL of diluent using a pipette to a tube containing detector granules.
- 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.
- 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.
 ⚠ 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 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.
- 7) Press 'Select' button on the instrument for ichroma™ tests to start the scanning process.
- 8) Instrument for ichroma™ tests should start scanning the sample-loaded cartridge immediately.
- 9) Read the test result on the display screen of the instrument for ichroma™ tests.

<Single Mode>

- 1) Transfer 150 µL of diluent using a pipette to a tube containing detector granules.
- 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.
- 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 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' or 'START' button on the instrument for ichroma™ tests.
- 7) Cartridge goes inside the Instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 12 min.
- 8) Read the test result on the display screen of the instrument for ichroma™ tests.
 (Please refer to the reader's operation manual for complete information and operation instructions.)

▶ AFIAS-50

- 1) Insert the tip array in the tip station.
- 2) Insert the detector array in the Reagent station and cover the reagent station.
- 3) Open the diluent and insert the diluent in the diluent station.
- 4) Open the cover of the magazine station and pull and lift the cartridge magazine.
- 5) Insert the cartridges in the cartridge magazine individually.
- 6) Insert the cartridge loaded cartridge magazine into the magazine station and close the cover of the magazine station.
- 7) Insert the sample tube into the blood collection tube rack and load the blood collection tube rack into the sampling station (loading part).
- 8) Tap the button located in the upper side of the No. of test

- cartridge region to select ID chip what you want to use.
- 9) When the selected cartridge slot is activated, set the number of test cartridge by tapping.
 - 10) Tap the button located in the upper side of the No. of reagent region to select ID chip what you want to use.
 - 11) When the selected slot is activated, set the number of Detector by tapping.
 - 12) Set the number of pipette tips by tapping.
 - 13) Tap the "START" button on the left upper of the main screen to start test.
- (Please refer to the AFIAS-50 operation manual for complete information and operation instructions.)

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 Plus 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 materials are not provided with ichroma™ PCT Plus. 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) 0.01 ng/mL
 - Limit of Detection (LoD) 0.02 ng/mL
 - Limit of Quantification (LoQ) 0.02 ng/mL
- Analytical specificity**
 - Cross reactivity
There was no significant cross-reactivity from these materials with the ichroma™ PCT Plus test measurements.

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

 - Interference
There was no significant interference from these materials with the ichroma™ PCT Plus test measurements.

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 umol/L
Heparin	3,000 U/L
Citrate	2 mg/mL

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

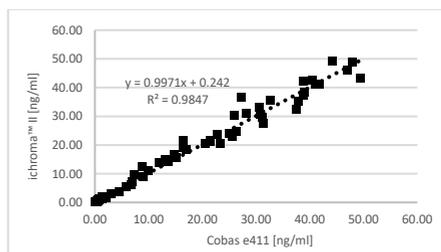
Conc. (ng/mL)	between Lot		between person		between day		between site	
	mean	CV (%)	mean	CV (%)	mean	CV (%)	mean	CV (%)
0.2	0.2	5.6	0.2	5.64	0.2	5.92	0.2	5.98
0.78	0.79	6.03	0.78	5.8	0.78	5.78	0.77	5.22
3.13	3.19	5.94	3.14	6.24	3.11	6.03	3.11	5.86

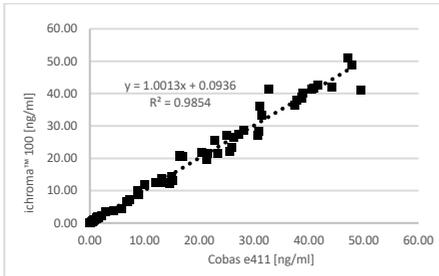
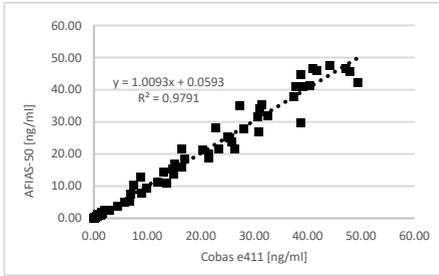
- Accuracy**
The accuracy was confirmed by 3 different lots testing ten times each different concentrations.

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**
PCT concentration of 100 standard materials were quantified independently with ichroma™ PCT Plus (ichroma™ II, AFIAS-50 and ichroma™ 100) 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.

	Cobas e411	
	Linear regression	coefficient of correlation (R)
ichroma™ II	$y = 0.9971x + 0.242$	0.9923
AFIAS-50	$y = 1.0093x + 0.0593$	0.9895
ichroma™ 100	$y = 1.0013x + 0.0936$	0.9927





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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
	Batch code
	Catalog number
	Caution
	Manufacturer
	Authorized representative of the European Community
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

For technical assistance; please contact:
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