



ichroma™ PSA

INTENDED USE

ichroma™ PSA is a fluorescence Immunoassay (FIA) for the quantitative determination of Prostate Specific Antigen (PSA) in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of prostate cancer or other prostate disorders.

For *in vitro* diagnostic use only.

INTRODUCTION

Prostate specific antigen (PSA), a neutral serine protease with chymotrypsin-like activity, is composed of a single polypeptide chain of 237 amino acids. It is an intracellular glycoprotein containing 7 – 8% carbohydrate as a single N-linked oligosaccharide side chain and has a molecular weight of approximately 34,000 Dalton.

PSA is exclusively synthesized by the prostate epithelium and mainly released into the semen. Normally very small amounts of PSA are secreted and detected in male blood. The elevated levels of PSA in male blood are known to be associated with some prostatic disorders such as prostatitis, benign prostatic hyperplasia (BPH) or prostate cancer.

PRINCIPLE

The test uses a sandwich immunodetection method.

The detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized antibodies- on a test strip.

More antigens in sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by the instrument for ichroma™ tests to show PSA concentration in sample.

COMPONENTS

ichroma™ PSA consists of 'cartridges', and 'detection buffes.

- The cartridge contains the membrane called a test strip which has anti human PSA at the test line, and streptavidin at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant, and they are further packaged in a cartridge box.
- The detection buffer contains anti-PSA-fluorescence conjugate, biotin-BSA-fluorescence conjugate, and sodium azide as a preservative in phosphate buffered saline (PBS). It is pre-dispensed in tubes. The detection buffer tubes are packaged in a detection buffer box and further packed in a styrofoam box with ice-pack for the shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions and procedures described in this

'Instructions for use'.

- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, detection buffer tube and ID chip) 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 of test result(s).
- Do not reuse cartridges or detection buffer tubes. A cartridge should be used for testing one sample only. A detection buffer tube should be used for processing 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 already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- If the test components and/or sample are stored in refrigerator, then allow cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used cartridges, detection buffer and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The detection buffer contains sodium azide (NaN₃), and it may cause certain health issues like convulsions, low blood pressure, low heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- **ichroma™ PSA** will provide accurate and reliable results subject to the below conditions.
 - **ichroma™ PSA** should be used only in conjunction with the instrument for ichroma™ tests.
 - Have to use recommended anticoagulant.

Recommended anticoagulant

K₂ EDTA, K₃ EDTA

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	4 – 30°C	20 months	Disposable
Detection buffer tube	2 – 8°C	20 months	Disposable

- 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 antigens to the antibodies which is the 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 antigens with time and/or temperature may also cause false negative result as it makes the antigens 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 in conjunction with clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF i-CHROMA PSA-25

Components of **ichroma™ PSA**

- Cartridge box:
 - Cartridge 25
 - 35 µL Capillary tube 25
 - ID chip 1
 - Instruction for use 1
- Detection buffer box:
 - Detection buffer tube 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately with **ichroma™ PSA**.

Please contact our sales division for more information.

- Instrument for **ichroma™** tests
 - **ichroma™ Reader** **REF** FR203
 - **ichroma™ II** **REF** FPRR021
- **Printer** **REF** FPRR007
- **Boditech Tumor marker Control** **REF** CFPO-94
- **Boditech PSA Control** **REF** CFPO-250

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ PSA** is human whole blood/serum/ plasma.

- It is recommended to test the sample within 24 hours after collection when collected sample is stored at room temperature.
- The samples (serum, plasma) should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- The samples (whole blood, serum, plasma) may be stored for a week at 2 – 8°C prior to being tested. If testing will be delayed more than a week, samples (serum, plasma) should be frozen at -20°C.
- The samples (serum, plasma) stored frozen at -20°C for 3 months showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.
- Whole blood sample can be collected using a capillary tube according to below:
 - ① Wear disposable gloves and protective equipment for safety.
 - ② Open the zipper bag which has capillary tubes.

- ③ Take out the capillary tube and check for damage or contamination.
- ④ Hold the handle of the capillary tube and touch the surface of blood with the capillary tube.
- ⑤ Fill it with blood completely.
(Make sure that no air bubbles are present in the capillary tube. Do not get blood on the surface of the capillary tube. If the blood gets on the surface of the capillary tube, remove it gently with gauze.)

TEST SETUP

- Check the contents of **ichroma™ PSA**: Sealed cartridges, detection buffer tubes, ID chip, 35 µL capillary tubes and an instructions for use.
 - Ensure that the lot number of the cartridges matches that of the detection buffer tube as well as the ID chip.
 - If the sealed cartridge and the detection buffer have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
 - Turn on the instrument for **ichroma™** tests.
 - Insert the ID chip into the 'ID chip port'.
- ※ **Please refer to the instrument for ichroma™ tests operation manual for complete information and operating instructions.**

TEST PROCEDURE

► **ichroma™ Reader, ichroma™ II**

Multi test mode / Read now mode

- 1) Select the sample type (whole blood or serum/plasma) on the screen.
- 2) Transfer 75 µL of sample (human serum/plasma/control) or 35 µL of sample (whole blood) using a pipette to detection buffer tube.
 - ※ If capillary tubes are used to collect whole blood, put the capillary tube filled with whole blood into the detection buffer tube.
- 3) Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times.
(The sample mixture must be used immediately.)
- 4) Take 75 µL of a sample mixture and dispense it into the sample well of the cartridge.
- 5) Leave the cartridge at room temperature for 15 minutes.
⚠ Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate 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 is marked on the cartridge especially for this purpose.
- 7) Press 'Select' button on the instrument for **ichroma™** tests to start the scanning process.
- 8) The instrument for **ichroma™** tests will start scanning the sample-loaded cartridge immediately.
- 9) Read the test result on the display screen of the instrument for **ichroma™** tests.

Single test mode/ Walk away mode

- 1) The test procedure is same with the 'Multi test mode 1) – 4)'.
- 2) Insert the sample-loaded cartridge into the 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 is marked on the cartridge especially for this purpose.
- 3) Press the 'Select' button on the instrument for ichroma™ tests.
- 4) The cartridge goes inside the instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 15 minutes.
- 5) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- The instrument for ichroma™ tests calculates the test result automatically and displays PSA concentration of the test sample in terms of ng/mL.
- **The cut-off (reference value): 4.00 ng/mL.** If the test result is above 4.00 ng/mL, please contact your physician immediately for more detailed investigation. The test result below 4.00 ng/mL does not completely exclude the possibility of a prostate disorder.
- Working range : 0.1 – 100 ng/mL (for serum/ plasma)
0.5 – 100 ng/mL (for whole blood)

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.
- 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 **ichroma™ PSA**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
(Please refer to the instructions for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Specificity:** There, in test samples, are biomolecules such as hemoglobin, bilirubin, triglyceride, ascorbic acid, glucose, carcinoembryonic antigen (CEA), alpha-fetoprotein (AFP), C-reactive protein (CRP), myoglobin, albumin and plasma/tissue kallikrein in higher concentration than their normal physiological levels. But this doesn't interfere with the **ichroma™ PSA** test measurements, nor occurs any significant cross-reactivity.
- **Precision:** The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **ichroma™ PSA**. The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing three times each different concentrations.

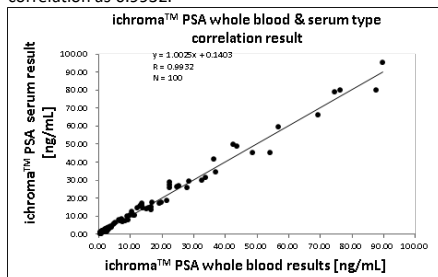
<Intra-assay of ichroma™ PSA>

PSA (ng/mL)	Serum/Plasma		Whole Blood	
	Mean	CV (%)	Mean	CV (%)
0.5	0.50	7.0	0.53	9.8
4	4.06	6.5	4.00	4.1
25	25.44	5.3	25.93	4.2

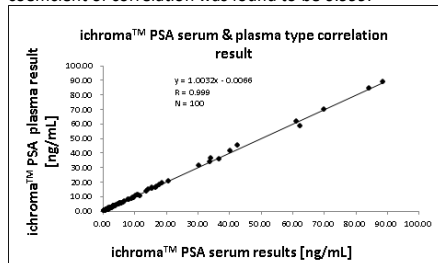
<Inter-assay of ichroma™ PSA>

PSA (ng/mL)	Serum/Plasma		Whole Blood	
	Mean	CV (%)	Mean	CV (%)
0.5	0.50	6.8	0.52	8.7
4	4.1	6.0	4.1	5.2
25	25.9	4.9	25.4	3.6

- **Correlation between test results of whole blood, serum and plasma samples:** The correlation between **ichroma™ PSA** test results was evaluated using 200 samples of whole blood and matching serum. The PSA concentration of each blood sample was compared with that of the corresponding serum. These 100 sets of PSA concentrations were measured and compared using a single lot of **ichroma™ PSA**, showing the coefficient of correlation as 0.9932.



Similarly, correlation between **ichroma™ PSA** test results from plasma samples and matching serum samples was also evaluated. Each blood sample was collected in two different test tubes; one treated with EDTA for obtaining the plasma sample and another without any anticoagulant treatment for the serum sample. 100 different set of plasma samples and matching serum were prepared and the PSA concentrations of each were measured and compared using a single lot of **ichroma™ PSA**. The coefficient of correlation was found to be 0.999.

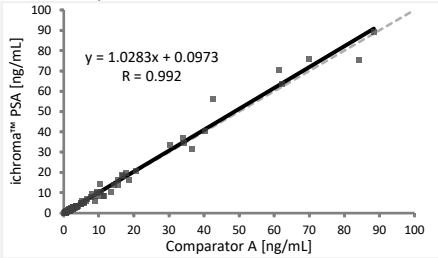


■ **Comparability**

PSA concentration of 100 clinical samples were quantified independently with **ichroma™ PSA (ichroma™ II)** and **comparator A** as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and correlation coefficient (R). The regression equation and correlation coefficient are as follows.

* Solid line: regression line of **ichroma™ PSA**

* Dash line: $y = x$



REFERENCES

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2. Woolf SH, Rothemich SF. SCREENING FOR PROSTATE CANCER: The Roles of Science, Policy, and Opinion in determining what is best for Patients. Annu. Rev. Med. 1999; 50:207-521.
3. Frankel S, Smith GD, Donovan J, Neal D. Screening for prostate cancer. Lancet 2003; 361:1122-1128.
4. Jung K, Klinggr P, Brux B, et al. Preanalytical Determinants of Total and Free Prostate-Specific Antigen and Their Ratio: Blood Collection and Storage Conditions. Clin. Chem. 1998; 44:685-688.

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
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse

For technical assistance, please contact:

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