



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 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 PSA concentration in sample.

COMPONENTS

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

- The cartridge contains a test strip, the membrane which has anti human PSA at the test line, while streptavidin 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 detection buffer contains anti human PSA-fluorescence conjugate, biotin-BSA-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™ PSA** 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™ PSA** will provide accurate and reliable results subject to the following conditions.
 - Use **ichroma™ PSA** should be used only in conjunction with instrument for ichroma™ tests.
 - Any anticoagulants other than EDTA 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 i-CHROMA PSA-25

Components of **ichroma™ PSA**

- Cartridge Box:
 - Cartridges 25
 - ID Chip 1
 - Instruction For Use 1
 - Capillary Tubes 25
- Box containing Detection Buffer tubes
 - Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

- Following items can be purchased separately from **ichroma™ PSA**. Please contact our sales division for more information.
- Instrument for ichroma™ tests

- **ichroma™ Reader** [REF](#) FR203
- **ichroma™ II** [REF](#) FPRR021
- **ichroma™ D** [REF](#) 13303
- **ichroma™ Printer** [REF](#) FPRR007
- **Boditech Tumor marker Control** [REF](#) CFPO-94

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.
- 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.
- However, the whole blood sample should not be kept in a freezer 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.
- Fingertip blood sample should be collected as follows:
 - Position the hand with the palm facing upwards. Blood should be normally drawn from the middle or ring finger of the non-dominant hand. Apply intermittent pressure towards its tip.
 - Wipe the fingertip clean with an alcohol pad.
 - Allow the finger to dry completely because blood will not form a drop if the puncture site is moist and because the residual alcohol at the fingertip may dilute the blood sample and affect the test result.
 - Hold the finger and puncture the fingertip by firmly pressing a new sterile lancet against it at an off-center position.
 - Wipe away the first drop of blood with a sterile gauze pad or cotton ball.
 - Massage the finger towards its tip to form a new drop of blood. Blood will flow easily if the finger is held lower than the elbow.
 - Hold the handle of a capillary tube and touch the mouth of the capillary to the drop of blood.
 - Let the blood fill the capillary tube completely.
 - It may be sometimes necessary to massage the finger again for an additional drop of blood for filling the capillary tube.

TEST SETUP

- Check the contents of **ichroma™ PSA**: Sealed Cartridge, Detection Buffer Tubes, ID Chip and Capillary Tubes.
- 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 75 µL of sample (human serum/plasma/control) using a transfer pipette to a tube containing the detection buffer. If the test is to be performed on whole blood, transfer the fingertip blood (collected in a capillary tube) to the detection buffer tube.

- 2) 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.)
- 3) Pipette out 75 µL of a sample mixture and dispense it into the sample well on the cartridge.
- 4) Leave the sample-loaded cartridge at room temperature for 15 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 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 the further 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.
- 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™ PSA**. 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

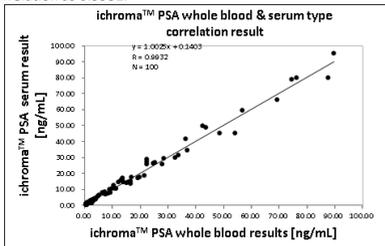
- **Specificity:** There, in test samples, are biomolecules such as hemoglobin, bilirubin, triglyceride, ascorbic acid, glucose, carcinoembryonic antigen (CEA), alpha-fetoprotein (AFP), C-reactive protein (CRP), myoglobin, albumin and plasma/tissue kallikrein in higher concentration than their normal 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.

| PSA (ng/mL) | <Intra-assay of ichroma™ PSA > | | | | |
|----------------|---------------------------------------|--------|-------------|--------|--------|
| | Serum/Plasma | | Whole Blood | | CV (%) |
| | 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 | |

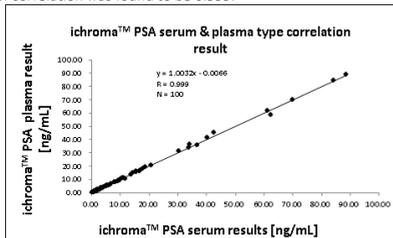
<Inter-assay of **ichroma™ PSA**>

| 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 |

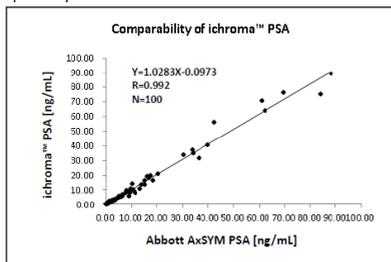
- **Correlation between test results of whole blood, serum and plasma samples:** The correlation between **ichroma™ PSA** test results was evaluated using 200 samples of whole blood and matching serum. The PSA concentration of each blood sample was compared with that of the corresponding serum. These 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 concentrations of 100 serum samples were quantified independently with **ichroma™ PSA** and Abbott AxSYM system (Abbott Laboratories, USA) 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 were $Y = 1.0283X - 0.0973$ and $R = 0.992$ respectively.



REFERENCES

1. Brooks DE, Devine DV, Harris PC, et al. RAMP(TM): A rapid, quantitative whole blood immunochromatographic platform for point-of-care testing. Clin. Chem. 1999; 45:1676-1678.
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 |
|  | 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 |

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