Tumor

ichroma™ PSA Neo

INTENDED PURPOSE

ichroma™ PSA Neo is an automated fluorescence immunoassay (FIA) for the quantitative determination of PSA (Prostate Specific Antigen) in human whole blood/serum/plasma. It is useful as an aid to the diagnosis 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 the 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 the sample.

COMPONENTS

ichroma™ PSA Neo consists of 'cartridges', 'detector tubes', and 'detector diluent'.

- The cartridge contains the membrane called a test strip which has anti-PSA at the test line and rabbit IgG at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant, and they are further packaged in a box.
- The detector tube has a granule containing anti-PSA-biotin conjugate, streptavidin-fluorescence conjugate and anti-rabbit IgG-fluorescence conjugate and sodium azide as a preservative in phosphate buffer saline (PBS). All detector tubes are packed in a pouch.
- The detector diluent contains tween 20 as a detergent and sodium azide as a preservative in Tris-HCl, and it is pre-dispensed in a vial. The detector diluent is packed in a box.

WARNINGS AND PRECAUTIONS

- Follow the instructions and procedures described in this 'Instructions for use'.
- Handle all the specimens as if they contain infectious agents.
- Due to the risk of infection, it is recommended to wear protective gear, including a mask and gloves, and handle the specimens and samples with utmost care during the test.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, detector tube, detector diluent and ID chip) must match each other.
- Do not interchange 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, detector tubes and capillary tubes. Each cartridge and capillary tube should be used for testing one sample only. A detector tube should be used for processing one sample only.
- Do not reuse pipette tips. Reusing pipette tips can lead to cross-contamination, resulting in erroneous test outcomes.
- The cartridge should remain sealed in its original pouch until just before use. Do not use a cartridge, if the pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- If test components and/or sample are stored in a refrigerator, then allow the cartridge, detector tube, detector diluent and the sample to reach room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used cartridges, detector tubes, detector diluent, capillary tubes and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The detector tube and the detector diluent contain sodium azide (NaN_3), 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.
- No Biotin interference was observed in **ichroma™ PSA Neo** when biotin concentration in the sample was below 100 ng/mL. If a patient has been taking biotin at dosage of more than 0.03 mg a day, it is recommended to collect blood again 24 hours after discontinuation of biotin intake.
- **ichroma™ PSA Neo** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ PSA Neo** should be used only in conjunction with the instrument for ichroma™ tests.
  - Have to use recommended anticoagulant.

Recommended anticoagulant
K_3 EDTA, Sodium heparin

- **The capillary tube should be used when the following conditions are met.**
  - The capillary tube provided with the kit is recommended to obtain correct test result.
  - Whole blood should be immediately tested after collection.
  - Excess whole blood around the capillary tube should be wiped off.
  - In order to avoid cross-contamination, please do not reuse capillary tube for multiple samples.

LIMITATIONS OF THE TEST SYSTEM

- The test is intended for use by healthcare professionals in a laboratory environment, not intended for near-patient testing.
- 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.

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 – 30°C	20 months	Disposable
Detector tube	2 – 30°C	20 months	Disposable
Detector diluent	2 – 30°C	20 months	Unopened
		20 months	Opened

- After the cartridge pouch is opened, the test should be performed immediately.

COMPONENT OPTIONS

ichroma™ PSA Neo is available in various component options. Please refer to the 'MATERIALS SUPPLIED' for the components included in each option according to that reference number.

REF CFPC-157	
REF CFPC-157CO01	REF CFPC-157CO01-1
REF CFPC-157CO05	REF CFPC-157CO05-1
REF CFPC-157CO10	REF CFPC-157CO10-1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

Please contact our sales division for more information.

- **Instrument for ichroma™ tests**
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FPRR021
  - **ichroma™ III** REF FPRR037
  - **ichroma™ M3** REF FPRR035
  - **ichroma™-50 PLUS** REF FPRR036
- **Printer** REF FPRR007
- **Boditech PSA Control** REF CFPO-250

SAMPLE COLLECTION AND PROCESSING

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

- It is recommended to test the sample (whole blood, serum, plasma) 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 components of **ichroma™ PSA Neo** according to the component options.
- Ensure that the Lot number of the cartridge matches that of the detector tubes, the detector diluent as well as an ID chip.
- If the sealed cartridge, the detector tube and the detector diluent 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, ichroma™ M3

Multi test mode

1) Select the sample type (whole blood or serum/plasma) on the screen.
   ※ If using control as the sample, select the 'serum/plasma'.
2) Take 150 µL of the detector diluent using a pipette and dispense it to the detector tube containing a granule. When the granule form is completely dissolved in the tube, it becomes detection buffer.
   (The detection buffer must be used immediately. Do not exceed 30 seconds.)
3) Take 30 µL of sample (serum/plasma/control) or 35 µL of sample (whole blood) using a pipette and dispense it to the detector tube.
   ※ When using the capillary tubes, collect the sample (whole blood) and put the capillary tube in the dissolved detector tube.
4) 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. Do not exceed 30 seconds.)
5) Take 75 µL of the sample mixture and dispense it into the sample well of the cartridge.
6) 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.***
7) 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.
8) Press the 'Select' or tap the 'Start' button on the instrument for ichroma™ tests to start the scanning process.
   (ichroma™ M3 will start the test automatically after inserting.)
9) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
10) Read the test result on the display screen of the instrument for ichroma™ tests.

Single test mode

1) The test procedure is same with the 'Multi test mode 1) – 5)'.
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' or tap the 'Start' button on the instrument for ichroma™ tests.
   (ichroma™ M3 will start the test automatically after inserting.)
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.

► ichroma™ III

1) The test procedure is same with the 'Single test mode'.

► ichroma™-50 PLUS

1) Insert the tip array in the tip station.
2) Insert the detector tube in the reagent station and cover the reagent station to hold the detector tubes in place.
3) Open the lid of the detector diluent and insert the detector diluent in the diluent station.
4) Insert the cartridge magazine with the cartridges into the magazine station.
5) Insert the sample tube into the blood collection tube rack and load the blood collection tube rack into the sampling station (loading part).
6) Tap the button located in the upper side of the No. of test cartridge region to select the ID chip that you want to use.
7) When the selected cartridge slot is activated, set the number of the detector tube by tapping.
8) Set the number of pipette tips by tapping.
9) Select the sample type (whole blood or serum/plasma) on the screen.
10) Tap the 'Start' button on the left upper of the main screen to start test.

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.
- Reference value: < 3.8 ng/mL
- Working range: 0.1 – 100 ng/mL

QUALITY CONTROL

- Traceability: This method has been standardized against CERTIFIED REFERENCE MATERIAL BCR® – 613.
- 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.
- The control material may be provided as needed. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.

PERFORMANCE CHARACTERISTICS

Analytical performance

1. Analytical sensitivity

Limit of Blank (LoB)	0.03 ng/mL
Limit of Detection (LoD)	0.05 ng/mL
Limit of Quantitation (LoQ)	0.10 ng/mL

2. 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. **ichroma™ PSA Neo** test results did not show any significant cross-reactivity with these biomolecules.

Cross-reactants	Concentration
CEA	500 ng/mL
AFP	1,000 ng/mL
Albumin	60 g/L
Kallikrein Protein	100 ng/mL

- **Interference**

Interferents listed in the following table were added to the test sample at the concentration mentioned below. **ichroma™ PSA Neo** test results did not show any significant interference with these materials.

Interferents	Concentration
Hemoglobin	10 g/L
Bilirubin, unconjugated	684 µmol/L
Triglycerides	1,500 mg/dL
Ascorbic acid	5.25 mg/dL
Glucose	1,000 mg/dL

3. Precision

- **Single-site study**

Repeatability (within-run precision)
within-laboratory precision (Total precision)
Lot to lot precision

3 Lots of **ichroma™ PSA Neo** were tested for 20 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.

PSA [ng/mL]	Repeatability		Within-laboratory precision		Lot to lot precision	
	AVG	CV	AVG	CV	AVG	CV
0.50	0.50	5.8%	0.50	5.6%	0.50	5.7%
4.00	4.00	5.7%	3.99	5.7%	3.97	5.9%
60.00	60.29	6.9%	59.72	6.2%	59.70	6.0%

- **Multi-site study**

Reproducibility

1 Lot of **ichroma™ PSA Neo** was tested for 5 days in 3 different sites (1 person per 1 site, 1 instrument per 1 site). Each standard material was tested 1 time per and 5 replicates per day.

PSA [ng/mL]	Reproducibility	
	AVG	CV
0.50	0.50	6.0%
4.00	3.97	5.8%
60.00	60.19	5.5%

4. Accuracy

The accuracy was confirmed by testing with 3 different Lots of **ichroma™ PSA Neo**. The tests were repeated 10 times at each concentration of the control standard.

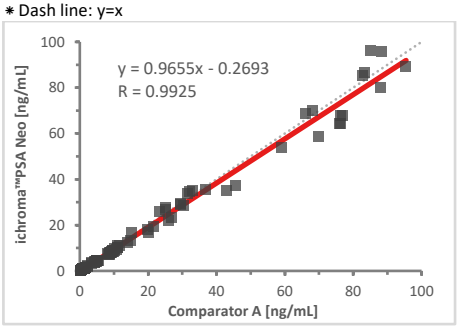
PSA [ng/mL]	Lot 1	Lot 2	Lot 3	AVG	Recovery
60.00	59.96	60.03	61.00	60.33	101%
48.10	48.51	47.08	49.01	48.20	100%
36.20	35.87	36.27	37.28	36.47	101%
24.30	24.77	24.43	24.89	24.69	102%
12.40	12.51	12.53	12.40	12.48	101%
0.50	0.51	0.49	0.50	0.50	100%

Clinical performance

1. Comparability

PSA concentrations of 100 clinical samples were quantified independently with **ichroma™ PSA Neo (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 Neo
✳ Dash line: y=x



MATERIALS SUPPLIED

Component		Reference number (Catalog number)						
		CFPC-157	CFPC-157CO01	CFPC-157CO05	CFPC-157CO10	CFPC-157CO01-1	CFPC-157CO05-1	CFPC-157CO10-1
■ ichroma™ PSA Neo	Cartridge	25	25	25	25	25	25	25
	Detector tube	25	25	25	25	25	25	25
	Detector diluent	1	1	1	1	1	1	1
	35 µL Capillary tube	25	25	25	25	25	25	25
	ID chip	1	1	1	1	1	1	1
	Instructions for use	1	1	1	1	1	1	1
■ Boditech PSA Control	Boditech PSA Control Level 1		1	5	10			
	Boditech PSA Control Level 2		1	5	10			
	Instructions for use		1	5	10			
	Control value & Barcode sheet		1	5	10			
■ Boditech Tumor marker Control	Boditech Tumor marker Control Level 1					1	5	10
	Boditech Tumor marker Control Level 2					1	5	10
	Instructions for use					1	5	10
	Control value & Barcode sheet					1	5	10

REFERENCES

1. McNeilly AS. Prolactin and the control of gonadotrophin secretion in the female. J Reprod Fertil. 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.

	Contains sufficient for <n> tests
	Consult instructions for use
	Use-by date
	Date of manufacture, Made in Korea
	Batch code
	Catalog number
	Caution
	Manufacturer
	Importer
	Distributor
	Authorized representative in the European Community
	*In vitro* diagnostic medical device
	Temperature limit
	Do not re-use
	This product fulfills the requirements of the Regulation (EU) 2017/746

<u>Any serious incident that has occurred in relation to this product shall be informed to Boditech Med Inc. and your competent authority.</u>

The Summary of Safety & Performance Report can be found here: https://ec.europa.eu/tools/eudamed

For technical assistance, please contact:
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