tPSA FIA Test | REF F2003 | Serum

For *in vitro* diagnostic use only. For professional use only.

INTENDED USE

The total Prostate Specific Antigen (tPSA) Fluorescence ImmunoAssay (FIA) Test is a lateral flow chromatographic fluorescence immunoassay for the quantitative detection of total PSA in human serum using the *RaFIA* system. This test is intended for *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION OF THE TEST

PSA is a protein secreted by the epithelial cells of the prostate gland. It is found at low levels in healthy men but is often elevated in prostate cancer or other prostate disorders. However, prostate cancer can also be present in the complete absence of an elevated PSA level. Therefore, PSA is not a unique indicator of prostate cancer. PSA levels can also be increased by prostatitis, irritation, benign prostatic hyperplasia (BPH), and recent ejaculation, producing a false-positive result[1-4].

TEST PRINCIPLE

This test is a fluorescent lateral flow immunoassay. When the specimen and the buffer are mixed and applied into the test device, the PSA present in the specimen and the mouse anti-PSA monoclonal antibody labeled with fluorescent reporters form an intermediate complex. The intermediate complex moves along the nitrocellulose membrane by lateral flow to a detection line (T-line) coated with PSA specific monoclonal antibodies. The intermediate complex will be captured by the antibodies coated on the T-line to form the final fluorescent reaction compound sandwich. Thus, the fluorescent signal on the detection line is positively correlated with the concentration of PSA in human serum.

The fluorescent signal from the reporters of the compound sandwich will be detected and calculated according to the calibration curve in the secure digital (SD) card (provided with the reagents), to represent the concentration of PSA in human specimens.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One test device
   b. One desiccant
2. Detection buffer tubes
3. SD card
4. Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. *RaFIA* Immunofluorescence Analyzer
3. *RaFIA* Immunofluorescence Incubator

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied.

1. Store the detection buffer and test device at 2-30°C.
2. Use the test device within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Step 1: Collect venous blood by venipuncture into a collection tube containing no anticoagulants, to prepare serum.

Step 2: Allow blood to clot, centrifuge the collected specimen and carefully withdraw the serum into a new pre-labeled tube.

Step 3: Test specimens immediately after collection or store refrigerated at 2-8°C for up to 5 days. Specimens can be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles.

Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Note: Do not test specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

Read these instructions and the instrument manual carefully before testing.

Please refer to the operation manual of the *RaFIA* Immunofluorescence Analyzer and *RaFIA* Immunofluorescence Incubator for details.

Step 1: Bring the specimen and detection buffer to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.

Step 2: Turn on the incubator. Set incubation temperature to 25°C and incubation time to 15 minutes.

Step 3: Turn on the analyzer and insert SD card into the analyzer. Press "Test" and choose "Quick Test". Input the patient information, then press "Confirm".

Step 4: When ready to test, open the pouch and label the device with the specimen's ID number. Ensure that the lot number of the buffer and the test device match.

***Note:** Complete steps 4 and 5 within 1 minute to ensure the accuracy of the test results.*

Step 5: Add 20 µL of serum into the buffer tube. Mix the specimen well with detection buffer by tapping or inverting the tube.

Step 6: Load 80 µL of specimen mixture into the sample well of the device. Ensure that there are no air bubbles. Immediately insert the device into incubator and incubate for 15 minutes.

Step 7: After 15 minutes, pull out the test device, insert it into the analyzer and press "Start Test". The test result will be shown on the screen and printed automatically.

Step 8: Discard used devices after interpreting the result following local requirements governing the disposal of devices.

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 or:

- After opening a new test lot to ensure the test performance is not altered.
- Whenever there is any question concerning the validity of the test results.

Control materials are not provided with this kit. For more information regarding obtaining the control materials, contact CTK Biotech's Sales Division for assistance (Please refer to the instructions for use of control material).

INTERPRETATION OF ASSAY RESULT

Expected Values

A normal range of < 4.0 ng/mL tPSA is recommended. However, laboratories should establish their own diagnostic cut-off concentration based on the clinical practice at their respective institutions.

PERFORMANCE CHARACTERISTICS

1. **Range**

   Working range: 0.5-200.0 ng/mL

2. **Precision**

   Intra-lot Precision

   Intra-lot precision was determined by testing of tPSA reference materials using 10 test devices from the same lot. CV ≤ 15%.

   Inter-lot Precision

   Inter-lot precision was determined by testing of tPSA reference materials using 30 test devices from 3 consecutive lots randomly (10 test devices from each lot). CV ≤ 20%.

3. **Accuracy**

   tPSA control materials with three different concentrations were tested by every lot of test device, and the deviations were within ± 15%.

4. **Linearity**

   A serial concentration of tPSA reference materials at 0.5-200.0 ng/mL was tested, and the correlation coefficient (R) is ≥ 0.9900.

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WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only. For professional use only.

1. Read these instructions completely before performing the test. Failure to follow the instructions could result in inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay. Do not use if the pouch is damaged or not sealed. Do not use expired devices.
3. Lot number of buffer and test device must match.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use components from any other type of kit as a substitute for the components in this kit. Use the tPSA FIA Test in conjunction with CTK *RaFIA* instruments only.
6. Do not use hemolyzed blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other bloodborne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Read test results at 15 minutes after a specimen is applied to the sample well of the device.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

LIMITATIONS OF TEST

1. The test sample should be serum.
2. Follow the assay procedure and the interpretation of assay result sections closely when testing for the presence of elevated tPSA in serum from individual subjects. Failure to follow the procedure may give inaccurate results.
3. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies[5,6].
4. If the symptom is highly suspicious or persists, while the result from the tPSA FIA Test is normal or non-reactive, it is recommended to test with an alternative test method.
5. Some unknown 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 specimens.
6. The tPSA FIA Test should be considered as preliminary diagnostic tool only. In case of an abnormal result, consult a physician to discuss the test result and decide further course of action.

REFERENCES

1. Catalona WJ, Richie JP, Ahmann FR, et al. Comparison of digital rectal examination and serum prostate specific antigen in the early detection of prostate cancer: results of a multicenter clinical trial of 6,630 men[J]. J of Urology. 1994 ,151 (5): 1283-1290.
2. Thompson IM, Pauler DK, Goodman PJ, et al. Prevalence of prostate cancer among men with a prostate-specific antigen level < or = 4.0 ng per milliliter[J]. J of The New England Journal of Medicine.2004, 350 (22): 2239-2246.
3. Herschman JD, Smith DS, Catalona WJ. Effect of ejaculation on serum total and free prostate-specific antigen concentrations[J]. J of Urology. 1997,50 (2): 239-243.
4. Nadler RB, Humphrey PA, Smith DS, et al. Effect of inflammation and benign prostatic hyperplasia on elevated serum prostate specific antigen levels[J]. J of Urology. 1995,154 (2 Pt 1): 407-413.
5. Boscato, L.M. and M.C. Stuart, *Heterophilic antibodies: a problem for all immunoassays. J of* Clin Chem, 1988. **34**(1): 27-33.
6. Levinson,S.S., *Antibody multispecificity in immunoassay interference. J of* Clin Biochem, 1992. **25**(2): 77-87.

Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ_N	Tests per kit
2°C-30°C	Store between 2-30°C		Do not reuse		
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
13855 Stowe Drive
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PI-F2003 Rev A
Date released: 2020-12-23
English Version

For Export Only. Not for Resale in the USA.