SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	IVD *In vitro* Diagnostic Medical Device	This side up	Use by
Contains sufficient for <n> tests	REF Catalogue Number	LOT Batch Number / Lot Number	DEVICE Device

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

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0424/VER-02

FIAcheck™

PSA

Fluorescence Immunoassay for Quantitative detection of Prostate Specific Antigen (PSA) in Human Serum/Plasma

DEVICE

FOR IN VITRO DIAGNOSTIC USE ONLY

Store at 4°C to 30°C

INTENDED USE

FIAcheck™ PSA Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of Prostate Specific Antigen (PSA) in human serum/plasma.

INTRODUCTION

Human Prostate Specific Antigen (PSA) is a 33KD serine proteinase which, in human serum, is predominantly bound to alpha 1- antichymotrypsin (PSA-ACT) and alpha 2-macroglobulin (PSA-AMG). Trace amounts of alpha 1-antitrypsin and inter-alpha trypsin inhibitor bound to PSA can also be found. Any remaining PSA is in the free form (f-PSA). Current methods of screening men for prostate cancer utilize the detection of the major PSA-ACT form. Levels of 4.0 ng/ml or higher are strong indicators of the possibility of prostatic cancer. However, elevated serum PSA levels have also been attributed to benign prostatic hyperplasia and prostatitis, leading to a large percentage of false positive screening results. A potential solution to this problem involves the determination of free PSA levels. Preliminary studies have suggested that the percentage of free PSA is lower in patients with prostate cancer than those with benign prostatic hyperplasia. Thus, the measurement of free serum PSA in conjunction with total PSA, can improve specificity of prostate cancer screening in selected men with elevated total serum PSA levels, which would subsequently reduce unnecessary prostate biopsies with minimal effects on cancer detection rates.

PRINCIPLE OF THE TEST

FIAcheck™ PSA is based on principle of agglutination of antibodies/anti-sera with respective antigen in immuno-chromatographic format using fluorophores as signal generators. The **FIAcheck™ PSA** test device is coated with immobilized PSA mouse monoclonal antibody 1 on the test line, goat anti chicken IgY in control line and a mixture of PSA mouse monoclonal antibody 2 and Chicken IgY labelled with fluorescent microspheres on the binding pad.

PSA in sample binds to the PSA mouse monoclonal antibody 2 labelled with fluorescent microspheres in the binding pad.

The fluorescent labelled Ag-Ab complex moves forward due to capillary action and is captured by the immobilized PSA mouse monoclonal antibody 1 forming a double antibody sandwich and produces the test line.

Chicken IgY labelled with fluorescent microspheres binds with goat anti chicken IgY to produce the control line. When the **FIAcheck™** test device is inserted in the **FIAcheck™** analyzer, it scans both the test line and control line. The ratio of the two fluorescence values is used to calculate the concentration of the analyte present in the sample.

MATERIALS AND COMPONENTS

Materials provided with the test kits:

- **FIAcheck™ PSA** test device in a sealed pouch with desiccant.
- QR Code card for calibration.

Materials required but not provided

- Precision pipettes: 100µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- Digital Thermometer
- Stopwatch

STORAGE AND STABILITY

1. **FIAcheck™ PSA** kit is stable at 4°C to 30°C upto expiry date printed on the label. DO NOT FREEZE.
2. **FIAcheck™** Test device should be used within 30 minutes once the foil pouch is opened.
3. If the colour of the desiccant has changed from blue to pink or colourless at the time of opening the pouch, kindly discard the device and use another device.

SAMPLE COLLECTION

1. Only human Serum and Plasma samples should be used. Other bodily fluids and samples may not give accurate result.

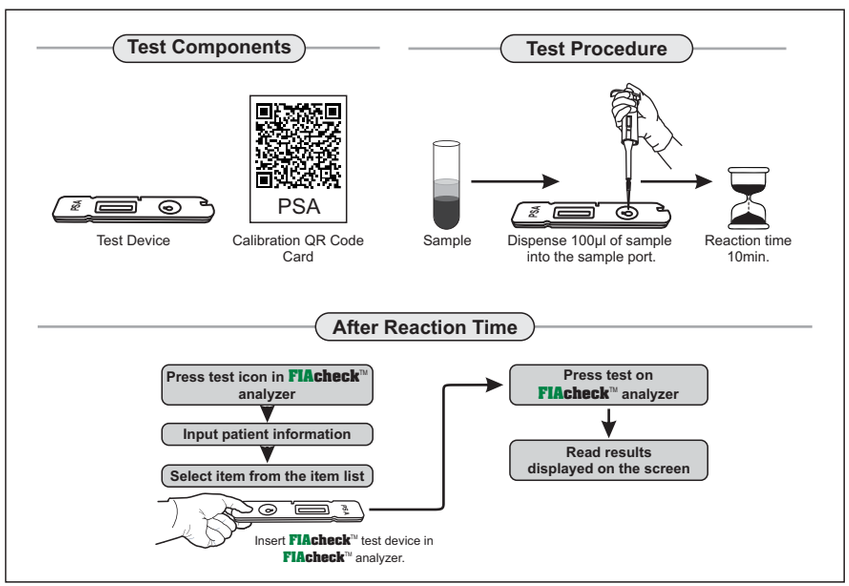
2. Plasma can be anti-coagulated with Heparin and Sodium citrate or Tri sodium citrate under aseptic conditions.
3. The test should be performed within 4 hours after the sample collection at room temperature.
4. Avoid grossly hemolytic, lipemic or turbid samples.
5. Preferably use fresh samples. However, samples can be stored for 3 days at 2°C to 8°C, and if more than 3 days, they should be stored at -20°C.
6. The sample should be recovered to room temperature (18°C to 30°C) before testing. Avoid repeated freezing and thawing of samples as it can affect test values.
7. Samples containing precipitate or particulate matter should be clarified by centrifugation prior to use.
8. Samples should be free from particulate matter and microbial contamination.

PRECAUTIONS

1. Only for In vitro diagnostic use.
2. After the test device is removed from the sealed pouch, it should be used immediately or within 30 minutes of opening the pouch.
3. Do not reuse the tested **FIAcheck**™ device.
4. Do not use damaged **FIAcheck**™ test device or pouch.
5. All samples should be considered potentially infectious and discarded appropriately as per Standard Bio-Safety guidelines.
6. Do not use kit after the expiry date.
7. Do not mix components of one kit with another.
8. Always use new tip for each sample.
9. Scan QR code card specific to the lot you are using.
10. Ambient temperature of testing environment directly impacts the accuracy of results. Ideal working temperature is 18°C to 30°C.
11. The **FIAcheck**™ test device should be read immediately after the specified reaction time. Delay in reading might affect the accuracy of results.
12. The **FIAcheck**™ test device should be used only in conjunction with **FIAcheck**™ analyzer for accurate and reliable results.

TEST PROCEDURE

1. To calibrate the **FIAcheck**™ **PSA** kit, scan the QR code card provided with the kit.
2. Remove **FIAcheck**™ **PSA** test device from sealed pouch and place it horizontally on a clean table, label the device with sample identity.
3. Dispense **100 µl** of sample onto the sample port of **FIAcheck**™ **PSA** test device.
4. Incubate at room temperature (18°C to 30°C) for **10 minutes**.
5. After 10 minutes, insert the test device immediately into the **FIAcheck**™ analyzer and read results.



Expected Range

Cut-Off Value: 4.0ng/mL

The cut-off value for PSA was determined by testing samples from 500 apparently healthy individuals. The 97.5th percentile of the concentration for PSA is 4.0ng/mL. According to different statistics method, the probability that value of a normal person below 4.0ng/mL is 97.5%.

It is recommended that each laboratory establish its own reference range for the population it serves.

PERFORMANCE CHARACTERISTICS

1. Measuring Range: 0.1-100ng/mL.
2. Lower Detection Limit: ≤0.1ng/mL.
3. Upper Detection Limit: ≥100ng/mL.
4. Accuracy: Based on comparison experiments, the relative standard deviation of ≤15%, and the correlation coefficient of r≥0.990 was observed.
5. Within-Run Precision: ≤15%.
6. Between-Run Precision: ≤15%.
7. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.
8. In an internal Study, **FIAcheck**™ **PSA** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIAcheck**™ **PSA** has demonstrated 100% clinical correlation with the commercially available licensed kit.

PSA Levels	No. of samples	FIAcheck™ PSA	EIA PSA
Normal	80	80	80
Low	8	8	8
High	12	12	12

9. In an external Study, **FIAcheck**™ **PSA** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIAcheck**™ **PSA** has demonstrated 100% correlation with the reference method.
   *Data file: Zephyr Biomedicals (A Division of Tulip Diagnostics (P) Ltd).

LIMITATIONS OF THE ASSAY

1. As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This kit is only for human serum and plasma.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose. In the event of performance changes or product malfunction, please contact manufacturer.

BIBLIOGRAPHY

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.
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3. Allard WJ, Zhou Z, Yueng KK. Novel immunoassay for the measurement of complexed prostate-specific antigen in serum. Clin, Chem. 1998, 44(6): 1216-1223.