PSA Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

PSA Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

PSA Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of PSA (Prostate Specific Antigen) in human serum and plasma. This test is used as an important indicator for monitoring the change of the condition of prostate cancer and observation of the curative effect.

[TEST PRINCIPLE]

PSA Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the PSA of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area.

When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. PSA test strip in a sealed pouch with desiccant.....25 tests
2. QR code card for calibration.....1 piece
3. User Manual.....1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. FIC-S100 Dry Fluorescence Immunoassay Analyzer
2. LS-1000 Dry Fluorescence Immunoassay Analyzer
3. LS-2000 Dry Fluorescence Immunoassay Analyzer
4. LS-1100 Dry Fluorescence Immunoassay Analyzer
5. LS-2100 Dry Fluorescence Immunoassay Analyzer
6. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
7. LS-7000 Microfluidic and Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum and plasma**. Other bodily fluids and samples may not get the accurate result.
2. Plasma can be anticoagulant with heparin and sodium citrate under aseptic conditions.
3. At room temperature, the test should be performed within 4 hours after the sample collection.
4. Serum or plasma sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
5. The sample before testing should be recovered to room temperature (15°C-30°C).
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to drop 100μL sample into the sample port in the test strip.
7. **Reaction Time: 10 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".

For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click "Test".

8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Cut-Off Value: 10.0ng/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 10.0ng/mL. According to different statistics method, the probability that value of a normal person below 10.0ng/mL is 97.5%.

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

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 100ng/mL, the analyzer displays ">100ng/mL", and if the result is less than 0.1ng/mL, the analyzer displays "<0.1ng/mL". Specific data can be exported through related software as needed.

2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. This kit is only for the serum and plasma test.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[PRODUCT PERFORMANCE]

1. Measuring Range: 0.1-100ng/mL.
2. Lower Detection Limit: ≤0.1ng/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.
6. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of linear range, and the detection result was greater than the upper limit of detection.

[PRECAUTIONS]

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[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.
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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.

Lansion Biotechnology Co., Ltd.

Add: No.2, Qiande Road, Jiangning District, Nanjing, China

Tel: 86-25-58577600

Fax: 86-25-58758600

E-mail: biz@lansionbio.com

Website: en.lansionbio.com

EC REP Llins Service & Consulting GmbH

Address: Am Heiligenhaus 7,69126, Heidelberg, Germany

Tel: +49 176 63866127

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Production date and expiration see the label.