**INSTANT-VIEW® PSA Semi Quantitative Whole Blood/Serum Test (Cassette)**

**Simple Assay**

**Rapid Visual Results**

**For Qualitative In Vitro Diagnostic Use**

**INTENDED USE**

The INSTANT-VIEW® PSA Rapid Test is a rapid lateral flow, semi-quantitative immunoassay. It is intended for use at point of care facilities to measure total prostate specific antigen (tPSA) in human whole blood or serum at a cutoff level of 4 ng/ml and with an analytical sensitivity of 1 ng/ml. Test results are to be used with other data by a physician as an aid to diagnosing prostate disease, monitoring the response of patients to therapy or detecting recurrent or residual disease in patients.

**SUMMARY AND EXPLANATION**

Prostate Specific Antigen (PSA) is an organ-specific antigen secreted primarily by the epithelial cells in the acini and ducts of the prostate gland. It may increase or decrease with changes in prostatic disease burden. Normally, the level of total PSA (tPSA) in human serum is in the range of 0.1–2.6 ng/ml. The common pathological cutoff level of tPSA in human serum is 4 ng/ml. Elevated serum tPSA is one of the important markers for prostate pathologies, such as benign prostatic hyperplasia (BPH), prostatitis, and prostate cancer.

Prostate cancer is the most prevalent cancer in men. According to the American Cancer Society, prostate cancer is the second-leading cause of cancer death among men in the country. Autopsy studies have shown that approximately one in three men over the age of 50 has histologic evidence of prostate cancer, with up to 80% of these tumors being microscopic in size or clinically insignificant. Fortunately, only about 3% of men will die from this disease.

This device is a semi-quantitative tPSA test for human whole blood or serum. This method is noninvasive; the assay procedures are easy and do not require professional training; the test provides a rapid result.

**TEST PRINCIPLE**

This assay is a chromatographic lateral flow, semi-quantitative immunoassay. The test strip in the device consists of 1) a burgundy-colored conjugate pad containing colloidal gold coupled with mouse anti-human PSA antibodies, and 2) nitrocellulose membrane containing a test (T) line, a reference (R) line, and a control (C) line. The T line is coated with mouse anti-human tPSA antibodies, the R line is coated with goat anti- chicken antibodies, and the C line is coated with goat anti-mouse antibodies.

The C line should always appear within 4 minutes, regardless of the presence of tPSA in the specimen. It serves as an internal qualitative control of the test system to indicate that an adequate specimen volume has been applied and the liquid migration occurred properly. The appearance of T line depends on the concentration of tPSA in the specimen tested.

If a specimen does not contain tPSA or contains tPSA below 1 ng/ml, the T line will not develop within 4-7 minutes, indicating a negative result; if a specimen contains tPSA at a level higher than 1 ng/ml, the T line will develop within 4-7 minutes, indicating a positive result. If a specimen contains tPSA at a level higher than 1 ng/ml, the T line will develop within 4-7 minutes, indicating a positive result. If a specimen contains tPSA at a level higher than 1 ng/ml, the T line will develop within 4-7 minutes, indicating a positive result.

The R line and the C line, should always appear within 4 minutes regardless of the presence of tPSA in the specimen. The R line serves as a criterion to indicate the concentration of tPSA is at 4 ng/ml. If the concentration of tPSA in the specimen is less than 4 ng/ml, the color intensity of T line will be weaker than that of the R line; if the concentration is higher than 4 ng/ml, the color intensity of T line will be stronger than that of the R line; if a specimen contains tPSA at a level around 4 ng/ml, the color intensity of T line is equivalent to that of the R line.

**MATERIALS AND REAGENTS PROVIDED**

- 23 test devices, each sealed in a pouch with a dropper pipette and a desiccant.
- 1 bottle of wash buffer- 7ml PBS diluent with 0.02% sodium azide as a preservative.
- 1 Package Insert (Instructions for Use)

**MATERIAL REQUIRED BUT NOT PROVIDED**

- Specimen containers and collection material
- Timer

**STORAGE**

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch containing desiccant.

Exposing the kit to the temperatures over 30°C may reduce the shelf life or damage the device. Freezing to -70°C (-94°F) will not cause damage to the device.

**Do not expose the kit to temperatures over 30°C (86°F).**

**PRECAUTION**

1. This kit is for professional in vitro diagnostic use only.
2. Do not pipette any material by mouth. Do not smoke, eat or drink in areas where specimens or reagents are handled.
3. Appropriate precautions are necessary in the collection and handling of specimens. Individuals performing the test should wear protective clothing such as laboratory coats and disposable gloves while collecting and testing samples and thoroughly wash hands afterwards.
4. Use a separate disposable pipette and test device for each specimen.

5. All spills should be wiped up thoroughly with sodium hypochlorite (0.5%), alcohol (70%) or an iodophor disinfectant.
6. Dispose of all specimens and used assay materials as biohazardous.
7. Avoid any contact between hands, eyes and nose during specimen collection and testing.
8. Do not mix reagents or components from different lots of test kits.
9. Do not use expired devices.

**SPECIMEN COLLECTION AND STORAGE**

1. Follow standard clinical procedures to collect fresh whole blood and serum specimens.
2. Finger-stick is recommended to collect fresh whole blood specimens for this assay. Wipe fingertip with alcohol, wait till the alcohol dries, then prick fingertip with a lancet in a quick motion.
3. Serum specimens can be stored at 20°C to 28°C (68 to 82°F) for 8 hours, at 2°-8°C (36-46°F) up to 7 days, and at -20°C (-4°F) or lower for long term storage. Repeatedly frozen and thawed specimens are not recommended for this assay.
4. Any sediment in serum specimens should be removed by centrifugation. Avoid using any turbid specimens, which may be contaminated by microorganisms.

**ASSAY PROCEDURE**

1. Refrigerated specimens and other test materials, including devices, must be equilibrated to room temperature before testing.
2. Remove the device from its pouch and label the device with specimen identification.
3. Holding the dropper vertically, add one drop of fresh blood or serum to the sample well marked “S”. Allow about 15 seconds for the specimen to be absorbed. Discard the first three drops of wash buffer from the wash buffer squeeze bottle. Then add three drops of wash buffer to the sample well.
4. Read the test result at 4 to 7 minutes after adding the specimen.

**IMPORTANT: Do not interpret the results after seven (7) minutes.**

**INTERPRETATION OF RESULTS**

**Positive:** A positive result indicates that the detection of PSA in the ranges identified below does not confirm a pathological state.

A. If all three lines are present, and the intensity of the T line is weaker than that of the R line, the test indicate a positive result: the level of tPSA is around or above 4 ng/ml.

B. If all three lines are present, and the intensity of the T line is close to that of the R line, the test indicate a positive result: the level of tPSA in the specimens is about 4 ng/ml.

C. If all three lines are present, and the intensity of the T line is stronger than that of the R line, the test indicate a positive result: the level of tPSA in the specimens is below 1 ng/ml.


## QUALITY CONTROL PROCEDURE

### Built-in Control Features
This test contains a built-in quality control feature, the C line. The appearance of the burgundy C line indicates that an adequate volume of specimen has been applied and the liquid migration occurred properly.

### External Quality Control
External controls are recommended, positive and negative, to monitor the proper performance of the assay.

### LIMITATIONS
This kit is designed as an aid in screening and monitoring, and should not be taken as a final diagnostic result.

### PERFORMANCE CHARACTERISTICS

#### A. Analytical Sensitivity
The analytical sensitivity of this device is 1 ng/ml.

#### B. Relative Sensitivity and Specificity
This device was evaluated off-site at three physician’s office laboratories (POL) and one medical reference laboratory (MRL). Three hundred and three (303) clinical serum specimens and nine (9) diluted specimens were used for this study. There were one hundred and ninety-two (192) positive and one hundred and twenty (120) negative. All the specimens were blindly labeled and tested by personnel with diverse educational backgrounds and working experience. The results are shown in the table below.

<table>
<thead>
<tr>
<th>Analytes</th>
<th>Concentration</th>
<th>Specimens</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Positive) *</td>
<td>(Negative) -</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>200 g/ml</td>
<td>+</td>
</tr>
<tr>
<td>Acetoclastic Acid</td>
<td>200 g/ml</td>
<td>+</td>
</tr>
<tr>
<td>Acetylalcoholic Acid</td>
<td>200 g/ml</td>
<td>+</td>
</tr>
<tr>
<td>Benzoylacetone</td>
<td>100 g/ml</td>
<td>+</td>
</tr>
<tr>
<td>Caffeine</td>
<td>200 g/ml</td>
<td>+</td>
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<tr>
<td>DMG</td>
<td>5%</td>
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<tr>
<td>EDTA</td>
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<td>+</td>
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<tr>
<td>Ethanol</td>
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<tr>
<td>Gentisic Acid</td>
<td>200 g/ml</td>
<td>+</td>
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<tr>
<td>p-Hydroxybutyrate</td>
<td>20 g/ml</td>
<td>+</td>
</tr>
<tr>
<td>Methanol</td>
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<tr>
<td>Phenothazine</td>
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<tr>
<td>Phenylpropanolamine</td>
<td>200 g/ml</td>
<td>+</td>
</tr>
<tr>
<td>Salicylic Acid</td>
<td>200 g/ml</td>
<td>+</td>
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</tbody>
</table>

#### E. Reproducibility

In-House Evaluation
Four serum samples, spiked with tPSA at the following concentrations, 0, 3, 5, 20 ng/ml, were tested in triplicate for twenty days, twice a day. All results obtained were 100% in agreement with the expected results. No within-run, between-run, within-day, or between-day discrepancy was observed.

Off-Site Evaluation
Reproductibility studies were also performed for INSTANT-VIEW® PSA Whole Blood/Serum Rapid Test at three physician’s office laboratories (POL). Eighty (80) serum samples spiked with tPSA at four different concentrations, 20 negative, 20 at 2 ng/ml, 20 at 6 ng/ml, and 20 at 20 ng/ml, were evaluated. Each sample was run in triplicate for three days at each POL. All the intra-assay agreement, the inter-assay agreement, and the inter-site agreement were 100%.

### REFERENCES