（**FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !**）

Prostate Specific Antigen Lateral Flow Assay Kit

Catalog No: E-HD-C063

20T/40T

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

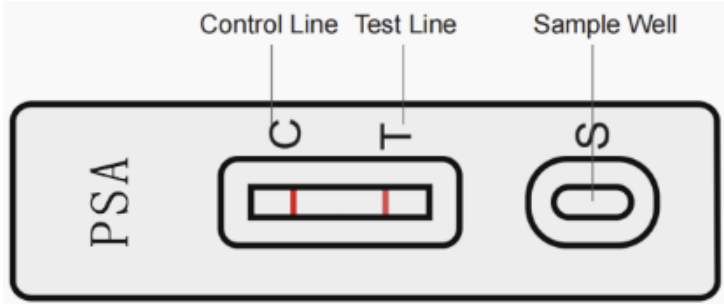
Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the test cassette. PSA, if present in the specimen, will bind to the PSA antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-PSA antibodies.

If the PSA level is higher than 4 ng/mL, the immunocomplex will form a visible burgundy colored T line .Absence of the T line suggests the PSA level is lower than 4 ng/mL.

The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of color development on the T line. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.



Kit components

Item	Specification
Detection Card	20T/40T
Sample diluent	1 bottle
Plastic droppers	20/40
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Please do not unpack the sealed pouch until you're ready to perform the test. If the package is obviously damaged, please do not use it.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15 ℃-30 ℃) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Hemolyzed blood may be used for the testing, but do not take precipitants.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.

8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne 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 biohazardous waste.
11. The testing results should be read within 30 minutes after a specimen is applied to the sample well or sample well of the device. Read result after 30 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow, ie.an electric fan or strong air-conditioning.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment.
Expiry date: expiration date is on the packing box.

Requirements of sample

The sample must be human serum, plasma, whole blood.

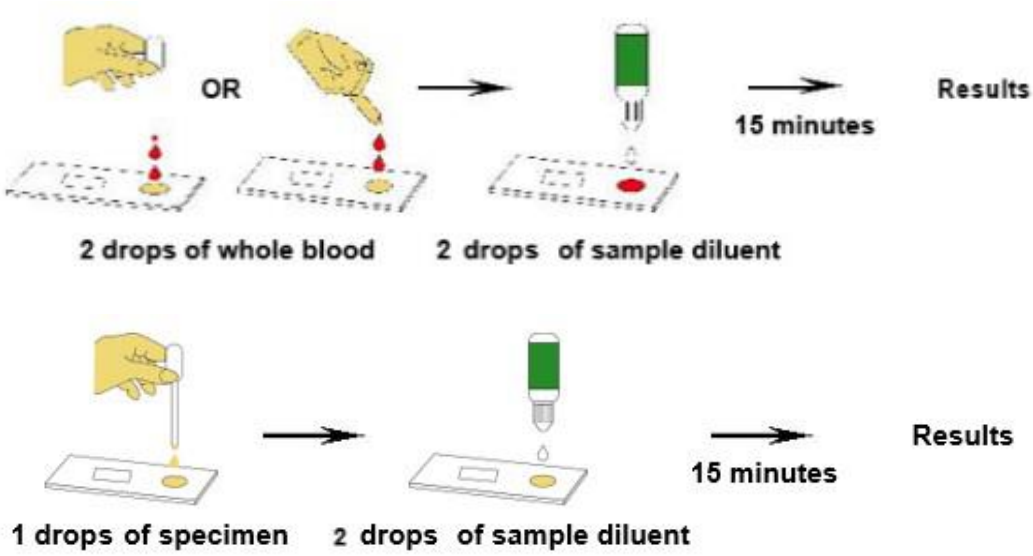
1. Hemolysis samples with ≥ 500 mg/mL hemoglobin, jaundice sample with ≥ 1.8 mmol/L bilirubin and high fat sample with ≥ 180 mmol/L glycerin trilaurate will interfere the detection with this kit.
2. Separate the serum immediately after collecting, and the prepared serum samples can be stored at 2-8℃ for 2 days or at -20℃ for a long-term storage..
3. Heat treated samples may interfere the detection result.
4. Don't use hemolysis, turbidity, hyperlipidemic or polluted samples. Avoid repeated freeze-thaw cycles. Otherwise, it will affect the accuracy of the results.
5. Consider any materials of human origin as infectious and handle them with standard biosafety procedures.
6. Collect whole blood in a clean container containing anti-coagulant (EDTA, citrate or heparin) by venipuncture. Blood can be obtained by fingertip puncture as well.
7. Whole blood specimen should be stored in refrigeration (2 ℃-8 ℃) if not tested immediately for up to 3 days. The specimen should be frozen at -20 ℃ for longer storage. Avoid repeat freeze and thaw cycles.

Assay procedure

Please read the operation manual completely and bring the test kit to room temperature (15 ℃ -30 ℃) before testing. The test should be performed at room temperature.

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.
2. When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
3. Be sure to label the device with the specimen's ID number.

4. **For whole blood test:** Apply 2 drops of whole blood (about 80-100 μL) to the sample well. Then add 2 drops (about 80-100μL) of sample diluent immediately. **For serum or plasma test:** Fill the plastic dropper with the specimen. Hold the dropper vertically and dispense 1 drop (about 30-45 μL) of specimen into the sample well, making sure that there are no air bubbles. Then add 2 drops (about 80-100 μL) of sample diluent immediately.



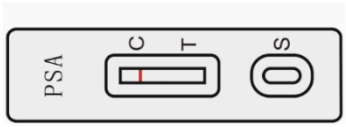
Note: This figure is for reference only.

5. Set up the timer.
6. Results can be read within 15 minutes.

Do not read the result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

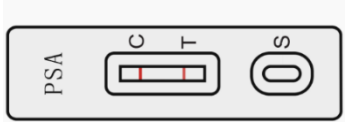
Interpretation of results

1.**Negative:** If only the C line developed, the test indicates PSA is not present or its level is less than the 4 ng/mL cutoff value. The result is negative.



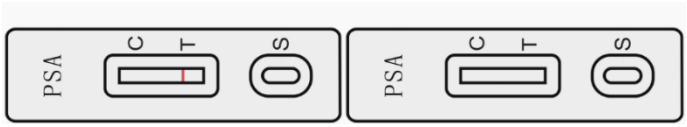
2.Positive

If the C, and T lines are all developed, the test indicates a PSA level is higher than 4 ng/mL. The result is positive.



(Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.)

3.**Invalid:** If the control line (C) fail(s) to appear the assay is invalid regardless of color development on the T line as indicated below. Review the procedure and repeat the assay with a new device.



NOTE: Pictures are for reference only.

Limitations of this test method

1. The Test Procedure and the Interpretation of Results sections must be followed closely when testing for the presence of elevated PSA in whole blood, serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Prostate Specific Antigen Test Kit is limited to the qualitative detection of PSA at a cut-off level of 3.0 ng/mL in human whole blood, serum or plasma. It should not be used as the sole criteria for the diagnosis of Prostate Cancer.
3. A significant number of patients with BPH (more than 15%) and less than 1% of healthy individuals have elevated PSA. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
4. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.
5. High concentrations of PSA may produce a dose hook effect resulting in false negative results. High dose hook effect has not been observed with this test up to 30,000 ng/mL PSA.