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

**Human PSEP Lateral Flow Assay Kit**

Catalog No: E-HD-C083

20T/40T

<b>Version Number:</b>	V1.0
<b>Replace version:</b>	V1.0
<b>Revision Date:</b>	2023.07.21

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](mailto:techsupport@elabscience.com)

Website: [www.vetassay-elab.com](http://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

The kit adopts the sandwich method. The test strip consists of: 1) a burgundy colored conjugate pad containing anti-PSEP antibody I conjugated with colloidal gold (anti-PSEP conjugates) and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with anti-PSEP antibody II, and the C line is pre-coated with a control line antibody.

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 cassette. PSEP, if present in the specimen, will bind to the anti-PSEP conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-PSEP antibody II forming a burgundy colored T line, indicating a PSEP positive test result.

Absence of the test lines suggests a negative result. The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of the control antibodies, regardless of color development on any of the test lines. Otherwise, the test result is invalid and the specimen must be retested with another device.

## Kit components

Item	Specification
Detection Card	20T/40T
Dropper	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. It is a disposable reagent, do not reuse it. Please use it within the validity date.
3. 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.
4. The reagent components of different batches cannot be mixed. Do not use components from any other type of test kit as a substitute for the components in this kit.
5. The desiccant in the aluminum foil bag shall not be taken orally.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Excessive high temperature of the experimental environment should be avoided. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
8. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
9. Too thin a urine sample can result in too low a concentration of PSEP in the urine, so it is not advisable to drink too much water or other beverages before testing. In addition, avoid drinking alcohol and expelling sperm before urinating.

10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. If you have any questions or suggestions during use, please contact the manufacturer.

### **Storage and expiry date**

**Storage:** Store at 4-30°C. With cool and dry environment.

**Expiry date:** expiration date is on the packing box.

### **Requirements of sample**

1. Specimen type: urine.
2. Specimens should be collected in a clean and dry container.
3. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For prolonged storage, urine specimens can be stably stored at -20°C for two months.

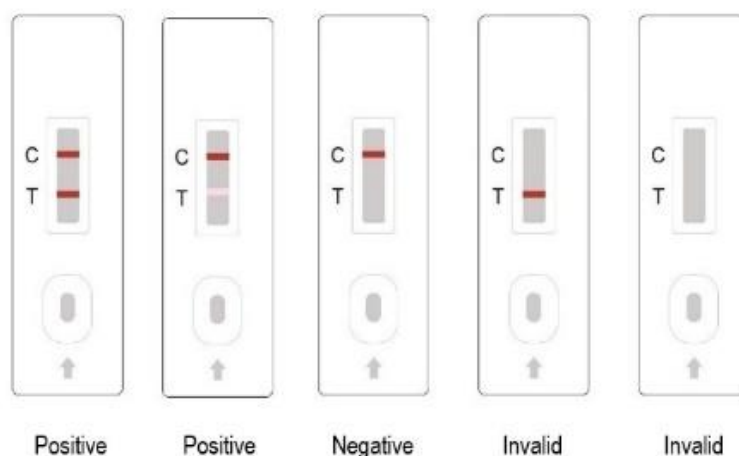
### **Assay procedure**

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. Draw enough specimen with a dropper, and then add 2 drops of urine specimen (approx.100 µL) vertically to the sample well (S) of the test cassette. Avoid trapping air bubbles in the sample well (S).
4. Set up the timer.
5. Read the result at 15 minutes. Results after 30 minutes should be considered invalid.

**To avoid confusion, discard the test device after interpreting the result.**

### **Interpretation of results**

1. Positive: in addition to one purplish red line in the control line (C) region, an apparent colored line will also appear in the test line (T) region.
2. Negative: only one purplish red line appears in the control line (C) region. No line appears in the test line (T) region.
3. Invalid: no line appears in the control line (C) region. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette.



Note: this figure is only used as a reference.

### Limitations of this test method

1. The test results of this reagent can only be used as an auxiliary tool, and the test results should be combined with other data.
2. Test results for the same sample using reagents from different manufacturers may differ due to methodological or antibody specificity reasons.
3. The test results may be affected by the personal cleanliness of the subject, drinking and eating.
4. The measured values by other methods are not directly comparable with the results determined by this reagent.