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

Human HP Antigen Lateral Flow Assay Kit

Catalog No: E-HD-C086

20T/40T

Version Number:	V1.1.2
Replace version:	V1.1.1
Revision Date:	2023.03.07

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

The HP Antigen Test Kit is a sandwich lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-HP antibody conjugated with colloidal gold (anti-HP 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 another monoclonal anti-HP antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of extracted fecal specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. HP antigens, if present in the specimen, will bind to the anti-HP conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibody forming a burgundy colored T line, indicating an HP positive test result. Absence of the T line suggests that the concentration of HP antigens in the specimen is below the detectable level, indicating an HP negative test result.

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 the 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
Stool Sampler	20/40 vials
Manual	1 copy

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

Notes

1. It is a disposable reagent. Do not reuse it. Please use it within the validity date.
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. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
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. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. The desiccant in the aluminum foil bag shall not be taken orally.
8. Do not scoop stool sample as this may lead to excess fecal specimen that tends to clot the sample pad and interfere with sample migration.
9. Extraction buffer contains 0.1% NaN_3. Avoid contact with skin or eyes. Do not ingest.
10. Users of this test should follow the US CDC Universal Precautions for biosafety.

11. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
13. The test results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the results after 15 minutes may give erroneous results.
14. All specimens, waste liquid and pipes are treated as infectious pollutants. After the test, the used test card should be discarded in the corresponding biohazard container and treated as a biohazard.
15. If you have any questions or suggestions during use, please contact the manufacturer.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment.

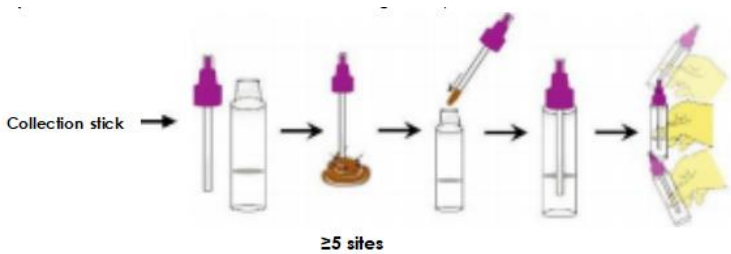
Expiry date: expiration date is on the packing box.

Requirements of sample

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

For solid stool samples

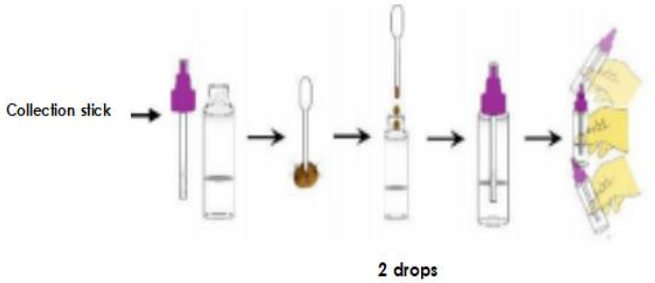
1) Collect a random stool sample in a clean, dry receptacle.
2) Open the stool sampler by unscrewing the top, and then use the collection stick to randomly pierce the stool sample in at least five different sites. Do not scoop stool sample as this may lead to an invalid test result.
3) Ensure stool sample is only in the grooves of the collection stick. Excess stool sample may lead to an invalid test result.
4) Replace the collection stick and tighten securely to close the stool sampler.
5) Shake the stool sampler vigorously.



The specimen is now ready for testing, transportation or storage.

For watery stool samples

1) Collect a random stool sample in a clean, dry receptacle.
2) Open the stool sampler by unscrewing the top.
3) Fill the plastic dropper with the sample; dispense 2 drops (70-90 μL) into the stool sampler.
4) Replace the collection stick and tighten securely to close the stool sampler.
5) Shake the stool sampler vigorously.



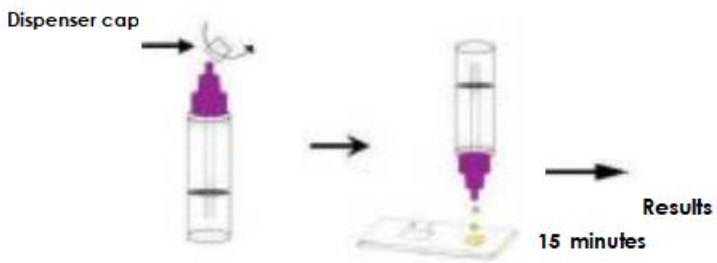
The specimen is now ready for testing, transportation or storage.

Note: Specimens extracted may be stored at 2℃-8℃ for up to 3 days. If longer storage is required, freezing at ≤ -20℃ is recommended.

Assay procedure

Please read the operation manual completely and bring the test reagent to room temperature (15℃-30℃) before testing. If the reagent is stored in the refrigerator, please take it out and equilibrate it to the room temperature in advance. The test should be performed at room temperature.

1. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
2. Shake the stool sampler vigorously to ensure a homogenous liquid suspension.
3. Position the stool sampler upright and twist off the dispenser cap. Holding the stool sampler vertically, dispense 2 drops of the solution into the sample well of the test device. Do not overload sample.
4. Set up the timer.
5. Interpretation: results can be read within 15 minutes after adding the specimen. Positive results can be visible in a time period as short as 1 minute.

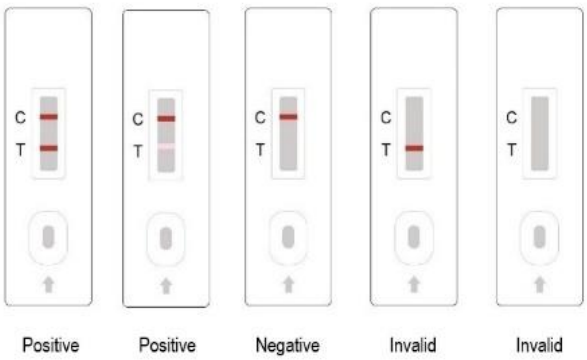


NOTE: This figure is only used as a reference. Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

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 Procedure and the Interpretation of Test Result sections must be followed closely when testing for the presence of HP antigen in feces. Failure to follow the procedure, particularly the Sample Requirements procedure, may cause inaccurate results.
2. The HP Antigen Test Kit is limited to the qualitative detection of HP antigen in human fecal specimen. The intensity of the test line does not have a linear correlation with the antigen titer in the specimen.
3. A negative result for an individual subject indicates the absence of detectable HP antigen. However, a negative test result does not preclude the possibility of infection with HP.
4. A negative result can occur if the quantity of the HP antigen present in the specimen is below the detection limits of the assay or if the antigens that are detected are not present in the fecal sample collected.
5. If symptoms persist and the result from the HP Antigen Test Kit is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with alternative test methods.
6. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.