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

Human Typhoid Antigen Lateral Flow Assay Kit

Catalog No: E-HD-C094

20T/40T

Version Number:	V1.1.3
Replace version:	V1.1.2
Revision Date:	2024.03.13

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 Typhoid Antigen Test Kit is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-S. typhi conjugated with colloidal gold (anti-S. typhi conjugates) and 2) a nitrocellulose membrane strip containing the T line and a control line (C line).The T line is pre-coated with monoclonal anti-S. typhi, 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 cassette, the specimen migrates by capillary action across the test cassette. The S. typhi antigen, if present in the specimen, will bind to the anti-S.typhi conjugate. The immunocomplex is then captured on the membrane by the pre-coated antibody forming a burgundy colored T line, indicating a Typhi Ag positive test result. Absence of the T line suggests a negative result. The test contain san internal control (C line) which should exhibit a burgundy colored line of the immune complex of the control antibodies, regardless of the color development on the T line. Otherwise, the test result is in valid, and the specimen must be retested with another device.

Kit components

Item	Specification
Detection Card	20T/40T
Stool Sampler	20/40 vials
Dropper	20/40 pieces
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. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not open the sealed pouch unless ready to conduct the assay.
4. Do not use expired devices.
5. Bring all reagents to room temperature (10 ℃-30 ℃) before use.
6. Do not use the components in any other type of test kit as a substitute for the components in this kit.
7. Do not use hemolyzed blood specimens for testing.
8. Wear protective clothing and disposable gloves while handling the kit reagents and specimens. Wash hands thoroughly after performing the test.
9. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
10. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as biohazard waste.

12. Handle the negative and positive controls in the same manner as patient specimens.
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 result after 20 minutes may give erroneous results.
14. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.
15. If you have any questions or suggestions during use, please contact the manufacturer.
16. The testing results should be read 15-20 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 15-20 minute window should be considered invalid and must berepeated.
17. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air conditioning.
18. If you have any questions or suggestions during use, please do not hesitate to 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.

Stool samples

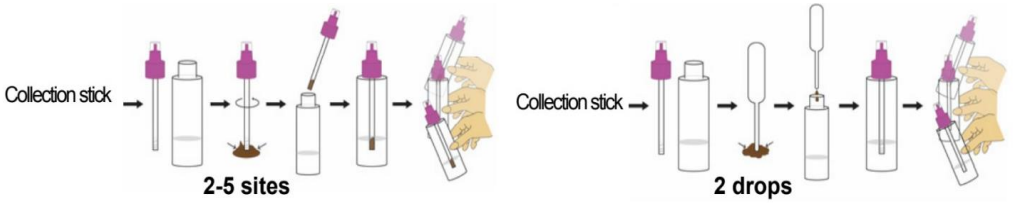
Step 1: Collect a random stool sample in a clean, dry receptacle.

Step 2: Open the stool sampler by unscrewing the top and 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.

Step 3: Ensure stool sample is only in the grooves of the collection stick. Excess stool sample may lead to an invalid test result.

Step 4: Replace the collection stick and tighten securely to close the stool collection device.

Step 5: Shake the stool collection device vigorously.



Plasma/Serum

Step 1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) for plasma or a red top collection tube (containing no anticoagulants) for serum by venipuncture.

Step 2: Separate the plasma by centrifugation.

Test specimens as soon as possible after collecting. Store specimens at 2-8℃, if not tested immediately. The specimens can be stored at 2-8℃ for up to 5 days. The specimens should be

frozen at -20℃ for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Whole blood

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively). Do not use hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2-8℃), if not tested immediately. The specimens must be tested within 24 hours of collection.

Assay procedure

For solid/watery fecal specimen

1. Shake the stool sampler vigorously to ensure a homogenous liquid suspension.
2. Hold the stool sampler vertically. Twist off the cap. Dispense 2 drops (70-90 μL) of the solution into the center of the sample well of the cassette, making sure that there are no air bubbles. Do not overload the solution.

For serum/plasma/whole blood specimen

3. Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 30-45 μL) of serum/plasma or 1 drop of whole blood (about 40-50 μL) into the sample well making sure that there are no air bubbles.
4. Immediately add 1 drop (about 35-50 μL) of extraction buffer to the sample well with bottle positioned vertically.

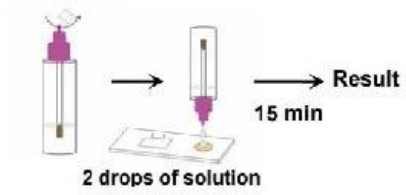


Fig.A

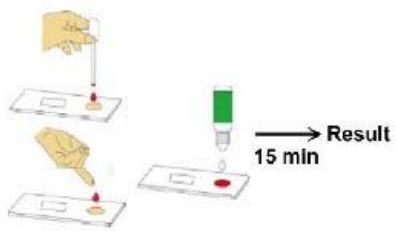


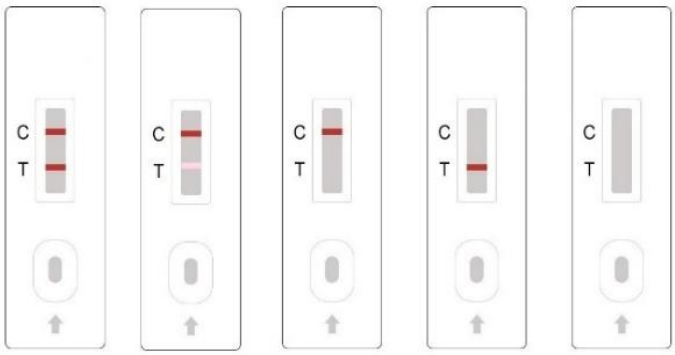
Fig.B

5. Set up the timer.
6. Results can be read at 15 minutes. Positive results can be visible in as short as 1 minute. Negative results must be confirmed at the end of the 20 minutes only. However, any results interpreted outside of the 15-20 minute window should be considered invalid and must be repeated.

Interpretation of results

Positive: If both C and T lines develop, the test indicates the presence of detectable RSV antigen in the specimen. The result is positive or reactive.

1. Negative: If only the C line is developed, the test indicates that no detectable RSV antigen is present in the specimen. The result is negative or non-reactive.
2. Invalid: If no C line develops, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new reagent.



NOTE: This figure is only used as a reference.

Limitations of this test method

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of S. typhi antigen in specimen from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Typhoid Antigen Test Kit is limited to the qualitative detection of S. typhi antigen in the specimen. The intensity of the test line does not have a linear correlation with the typhoid antigen titer of the specimen.
3. A nonreactive test result does not preclude the possibility of exposure to or infection with typhoid.
4. A nonreactive result can occur if the quantity of S. typhi antigen present in the specimen is below the detection limits of the assay or the typhoid antigens that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptoms persist while the result from Typhoid Antigen Test Kit is nonreactive, it is recommended to re-sample the patient a few days later or to test with an alternative method such as PCR or ELISA.
7. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.