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

Human Typhoid IgG/IgM Lateral Flow Assay Kit

Catalog No: E-HD-C095

20T/40T

Version Number:	V1.2.1
Replace version:	V1.2
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 Typhoid IgG/IgM Test Kit (Colloidal gold Assay) is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a burgundy colored conjugate pad containing recombinant H antigen and O antigen conjugated with colloidal gold (HO conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The M line is pre-coated with monoclonal anti-human IgM for the detection of IgM anti-S. typhi and paratyphi, the G line is pre-coated with reagents for the detection of IgG anti-S. typhi and paratyphi , and the C line is pre-coated with goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the test specimen migrates by capillary action across the test cassette. IgM/IgG antibodies, if present in the specimen, will bind to the HO conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM/IgG antibody forming a burgundy colored M/G line, indicating a S. typhi or paratyphi IgM/IgG positive test result.

Kit components

Item	Specification
Detection Card	20T/40T
Sample Diluent	1 bottle
Dropper	20T/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 (15-30℃) before use.
6. Do not use the components of any other type of test kit as a substitute for the components in this kit.
7. Do not use hemolyzed blood specimen 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 bio-hazardous waste.

12. The testing results should be read 15 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 15 minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
14. 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 plasma samples

1) Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture.
2) Separate the plasma by centrifugation.
3) Carefully withdraw the plasma into a new pre-labeled tube.

For serum samples

1) Collect blood specimen into a red top collection tube (containing no anticoagulants) by venipuncture.
2) Allow the blood to clot.
3) Separate the serum by centrifugation.
4) Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. If not tested immediately, store specimens at 2-8℃ for up to 5 days. For longer storage, specimens should be kept frozen at -20℃. 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 on result interpretation.

For whole blood samples

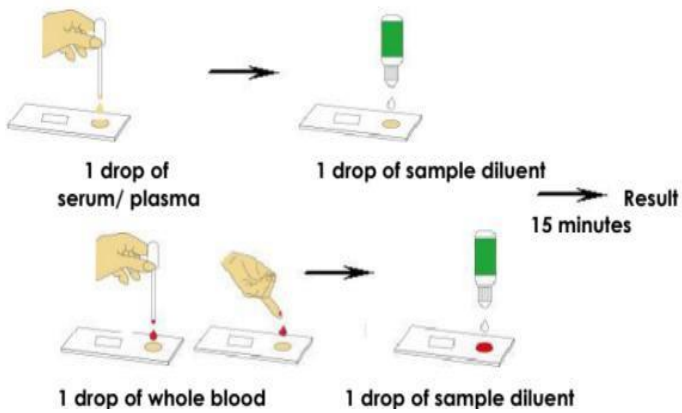
Drops of whole blood can be obtained by venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively). Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored at 2-8℃ if not tested immediately. The specimens must be tested within 24 hours of collection.

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. Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen 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 ID number.
4. Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop of serum/plasma (about 30-45 μL) or 1 drop of whole blood (about 45-55 μL) into the sample well, making sure there are no air bubbles. Immediately add 1 drop (about 35-50 μL) of sample diluent with the bottle positioned vertically.
5. Set up the timer.
6. Result can be read in 15 minutes. Positive results may be visible in as soon as 1 minute. Do not read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.



Note: this figure is only used as a reference.

Interpretation of results

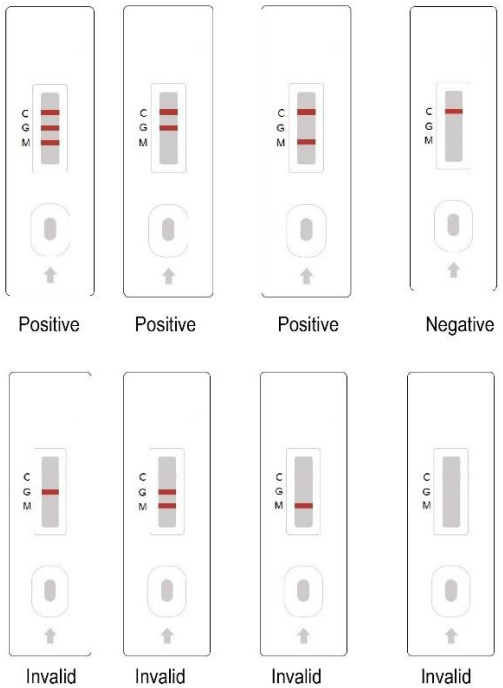
1. Positive

(1) In addition to the presence of C line, if only the G line develops, the test result indicates that IgG anti-Typhoid virus is detected.

(2) In addition to the presence of the C line, if only the M line is developed, the test indicates the presence of IgM anti-Typhoid in the specimen.

(3) In addition to the presence of C line, if test lines (G, M) appear color, indicating that IgG anti-Typhoid virus and IgM anti-Typhoid are both detected.

2. Negative: a purplish red band only appears on the quality control line (C).
3. Invalid: no purplish red band appears on the quality control line (C), indicating incorrect operation or deterioration of the reagent. In this case, please read the operation manual carefully again and retest with a new reagent.



NOTE: This figure is only used as a reference.

Limitations of this test method

1. The Test Procedure and Interpretation of Results must be followed closely when testing the presence of antibodies to Typhoid virus in serum, plasma and whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate results.
2. The Typhoid IgG/IgM Test Kit is limited to the qualitative detection of IgG and IgM anti-Typhoid virus in human serum, plasma and whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. Information about the Typhoid virus serotype(s) present in a specimen cannot be provided from this test.
4. The Typhoid IgG/IgM Test Kit cannot differentiate primary or secondary infection.
5. Serological cross-reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile virus, yellow fever, etc.). Therefore, it is possible that patients who were exposed to these viruses may show some level of reactivity with this test.
6. A negative or non-reactive result for an individual subject indicates absence of detectable Typhoid virus antibodies. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with Typhoid virus.
7. A negative or non-reactive result can occur if the quantity of antibodies to Typhoid virus present in the specimen is below the limits of detection, or if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
8. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

9. Infection may progress rapidly. If the symptoms persist, while the result from Typhoid IgG/IgM Test Kit is negative or non-reactive, it is recommended to test with an alternative test method.
10. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.