Typhoid IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A rapid test for the qualitative detection of Typhoid IgG/IgM Antibody in human serum, plasma or whole blood. For professional medical institutions use only.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

The Typhoid IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold) is a lateral flow immunoassay for the simultaneous detection and differentiation of anti-Salmonella typhi (S.typhi) IgG and IgM in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with S.typhi. Any reactive specimen with theTyphoid IgG/IgM Rapid Test Kit must be confirmed with alternative testing method(s).

SUMMARY

Typhoid fever is caused by S.typhi, a Gram-negative bacterium. World-wide an estimated 17 million cases and 600,000 associated deaths occur annually. Patients who are infected with HIV are at significantly increased risk of clinical infection with S.typhi. Evidence of H. pylori infection also presents an increase risk of acquiring typhoid fever. 1-5% of patients become chronic carrier harboring S.typhi in the gallbladder.

The clinical diagnosis of typhoid fever depends on the isolation of S.typhi from blood, bone marrow or a specific anatomic lesion. In the facilities that can not afford to perform this complicated and time-consuming procedure, Filix-Widal test is used to facilitate the diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test.

In contrast, theTyphoid IgG/IgM Rapid Test Kit is a simple and rapid laboratory test. The test simultaneously detects and differentiates the IgG and the IgM antibodies to S.typhi specific antigen in whole blood specimen thus aid in the determination of current or previous exposure to the S.typhi.

TEST PRINCIPLE

The Typhoid IgG/IgM Antibody Rapid Test Cassette is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant S. typhoid H antigen and O antigen conjugated withcolloid gold (Typhoid conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for the detection of IgM anti-S.typhi, G band is pre-coated with reagents for the detection of IgG anti-S.typhi, and the C band is pre-coated with goat anti rabbit IgG.

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. Anti-S.typhi IgM if present in the specimen will bind to the Typhoid conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored M band, indicating a S.typhi IgM positive test result.

Anti-S.typhi IgG if present in the specimen will bind to the Typhoid conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored G band, indicating a S.typhi IgG positive test result.

MATERIAL PROVIDED

Test Devices, each test cassette is packed in a foil pouch with a package of desiccant.
Droppers
Assay Buffer
Instructions for Use

MATERIALIS REQUIRED BUT NOT PROVIDED

Clock or Timer

PRECAUTIONS

For in Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (10°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for thecomponents in this kit.
6. Do not use hemolized blood specimen for testing.
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. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, ie. electric fan or strong air- conditioning.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.
The shelf-life of the kit under these storage conditions is 24 months.

SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

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

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.
5. Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°Cif not tested immediately.
6. Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

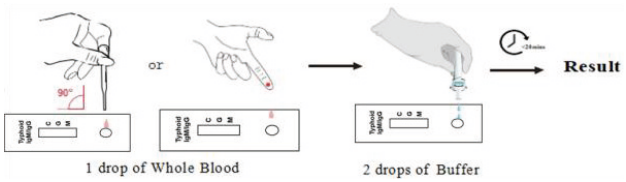
Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Donot use any hemolized blood for testing.

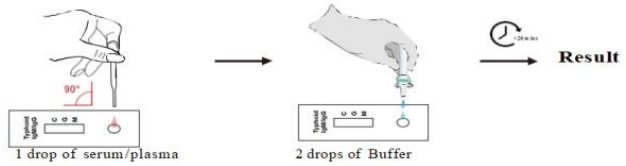
Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated orfrozen. Once thawed, mix the specimen well prior to assay.
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.
Step 4: **For whole blood test**
- Apply 1 drop of whole blood (about 25 µL) into the sample well.
- Then add 2 drops (about 60-70 µL) of Sample Diluent immediately.



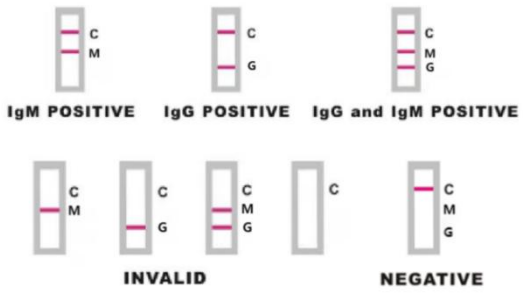
For serum or plasma test
- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30 µL-35 µL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 drops (about 60-70 µL) of Sample Diluent immediately.



Step 5:Set up timer.
Step 6: Results can be read in 20 minutes. Positive results can be visible in as shortas 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF ASSAY RESULT



Negative Result
If only the C band is present, the absence of any burgundy color in the both test bands (M and G) indicates that no anti-S.typhi antibody is detected. The result is negative.
Positive Result
IgG Positive: In addition to the presence of C band, if only G band is developed, thetest indicates for the presence of anti- S.typhi IgG. The result is positive.
IgM Positive: In addition to the presence of C band, if only M band is developed, the test indicates for the presence of anti- S.typhi IgM. The result is positive.
IgG/IgM Positive: In addition to the presence of C band, both M and G bands are developed, the test indicates for the presence of anti-S.typhi IgG and IgM. The result is also positive.
Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.
Invalid Result
If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands(G and M) as indicated below. Repeat the assay with a new device.

QUALITY CONTROL

Using individual Typhoid IgG/IgM Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:
1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C-30°C.
5. The temperature of the test area falls outside of 10°C-30°C.
6. Expected results are as follows:

Negative Control
Only the C band shows color development, the two test bands (M and G) show nocolor development.
Positive Control
The C band and two test bands (M and G) show color development.

LMITATIONS

1. The Assay Procedure and the Test Result Interpretation must be followed closelywhen testing the presence of antibodies to S.typhi in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Typhoid IgG/IgM Rapid Test Kit is limited to the qualitative detection of antibodies to S.typhi in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-S.typhi antibodies. However, a negative test result does not preclude the possibility of exposure to S.typhi.
4. A negative result can occur if the quantity of anti-S.typhi antibodies present in the specimen is below the detection limit of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE

1. Clinical Performance For IgM Test
A total of 234 samples from susceptible subjects were tested by the Typhoid IgG/IgM Rapid Test Kit and by a commercial S.typhi IgM EIA. Comparison for all subjects is showed in the following table:

	Typhoid IgG/IgM Rapid Test		
IgM EIA Test	Positive	Negative	Total
Positive	131	3	134
Negative	2	98	100
Total	133	101	234

Relative Sensitivity:97.67%
Relative Specificity:98.0%
Overall Agreement: 97.86%

2. Clinical Performance For IgG Test
A total of 214 samples from susceptible subjects were tested by the Typhoid IgG/IgM Rapid Test Kit and by a commercial S.typhi IgG EIA kit. Comparison for all subjects isshowed in the following table:

	Typhoid IgG/IgM Rapid Test		
IgG EIA Test	Positive	Negative	Total
Positive	113	1	114
Negative	2	98	100
Total	115	99	214

Relative Sensitivity:99.12%
Relative Specificity: 98.0 %
Overall Agreement: 98.60%

Code:GKPD037-1 Effective date: May 28, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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