ACCUCARE®

Salmonella typhi (IgG/IgM) Test

(Serum/Plasma/Whole Blood)

For rapid qualitative detection of both Salmonella typhi antibodies, IgG and IgM in human serum/ plasma / Whole Blood.
Only for *In Vitro* diagnostic use.

ORDER INFORMATION

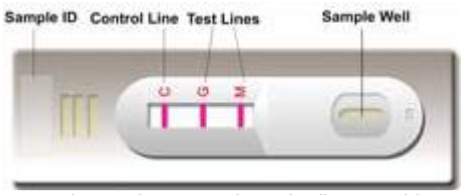
REF	Cont.
TABC 10	10 Test
TABC 25	25 Test

CLINICAL SIGNIFICANCE

Typhoid fever and paratyphi fever are bacterial infections caused by Salmonella Typhi and paratyphoid A, B, C respectively, which is transmitted through the ingestion of tainted food and water. 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. 1-5% of patients become chronic carriers harboring S. typhi in the gallbladder. The clinical diagnosis of infections depends on isolation of S. typhi and paratyphi from blood, bone marrow or a specific anatomic lesion. In facilities that can not afford to perform this complicated and time-consuming procedure, Filix-Widal test is used to facilitate diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test In contrast, the Accucare Typhoid IgG/IgM Rapid Test is a simple, fast laboratory test that simultaneously detects and differentiates IgG and IgM antibodies to S. typhi and paratyphi antigen thus aiding in the determination of current or previous exposure to S. typhi and paratyphi. IgM positive or IgM /IgG both positive suggest current infection, while IgG positive suggests late stage of infection, or previous infection, or latent infection.

PRINCIPLE

The Accucare Typhoid IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant H antigen and O antigen conjugated with colloid gold (HO conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (G and M 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 and paratyphi, G band is pre-coated with reagents for the detection of IgG anti-S. typhi and paratyphi , 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 cassette, the test specimen migrates by capillary action across the test cassette. IgM antibodies if present in the patient specimen will bind to the HO 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 or paratyphi IgM positive test result. IgG antibodies if present in the patient specimen will bind to the HO conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored G band, indicating a S. typhi or paratyphi IgG positive test result. Absence of any test bands (M and G) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and product insert

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 (15°C-30°C) 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. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The testing results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the test after 15 minutes may give erroneous results.

STORAGE & STABILITY

Store as packaged in the sealed pouch at 2-30 °C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze.

SPECIMEN COLLECTION & PRESERVATION

1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant .

2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card.

4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8 °C . For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30 °C) prior to use.

5)Avoid multiple freeze-thaw cycles. 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.

Directions for Use

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with specimen's ID number.
4. Fill the pipette dropper with the specimen.

Holding the dropper vertically, dispense 2 drop of specimen (Serum/Plasma/Whole Blood) into the sample well making sure that there are no air bubbles.
Then add 1 drop of buffer immediately.

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(Serum/Plasma/Whole Blood)

5. Set up timer.
6. Results can be read in 15-20 minutes.

Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

NEGATIVE OR NON-REACTIVE 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* or *paratyphi* antibody is detected in the specimen. The result is negative or non-reactive.

POSITIVE OR REACTIVE RESULT:

1. In addition to the presence of C band, if only M band is developed, the test indicates for the presence of anti- *S. typhi* or *paratyphi* IgM in the specimen. The result is IgM positive or reactive.

2. In addition to the presence of C band, if only G band is developed, the test indicates for the presence of anti- *S. typhi* or *paratyphi* IgG in the specimen. The result is IgG positive or reactive.

3. 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* or *paratyphi* IgG and IgM in the specimen. The result is both IgG and IgM positive or reactive.

Samples with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

INVALID: If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.

PERFORMANCE CHANACTERISTICS

1. Clinical Performance for IgM Test

A total of 334 samples from susceptible subjects were tested by the Accucare Typhoid IgG/IgM2.0 Rapid Test and by a commercial S. typhi IgM EIA. Comparison for all subjects is shown in the following table.

***Accucare* Typhoid IgG/IgM2.0 Rapid Test**			
IgM EIA	**Positive**	**Negative**	**Total**
Positive	31	3	34
Negative	2	298	300
Total	33	302	334

Relative Sensitivity: 91%, Relative Specificity: 99.3%, Overall Agreement: 98.5%

2. Clinical Performance For IgG Test

A total of 314 samples from susceptible subjects were tested by the Accucare Typhoid IgG/IgM2.0 Rapid Test and by a commercial *S. typhi* IgG EIA kit. Comparison for all subjects is shown in the following table.

***Accucare* Typhoid IgG/IgM2.0 Rapid Test**			
IgG EIA	**Positive**	**Negative**	**Total**
Positive	13	1	14
Negative	2	298	300
Total	15	299	314

Relative Sensitivity: 92.9%, Relative Specificity: 99.3%, Overall Agreement: 99.0%

3. Performance comparison with blood culture

Nine (9) *S. paratyphi* A and eleven (11) *S.typhi* specimens confirmed with the blood culture were tested with the *Accucare* Typhoid IgG/IgM2.0 Rapid Test. The Accucare Typhoid IgG/IgM2.0 Rapid Test correctly indentified 9 *S. paratyphi* A and 10 *S. typhi* specimens. The agreement was 95%.

LIMITATIONS

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to *S. typhi* or *paratyphi* in serum / plasma/ whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Accucare Typhoid IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to *S. typhi* or *paratyphi* in human serum/plasma/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* or *paratyphi* antibodies. However, a negative test result does not preclude the possibility of exposure to *S. typhi* or *paratyphi.*
4. A negative result can occur if the quantity of anti-*S. typhi* or *paratyphi* 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. If the symptom persists, while the result from Accucare Typhoid IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test method, such as bacterial culture method.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

BIBLIOGRAPHY

1. Ivanoff BN, Levine MM, Lambert PH. Vaccination against typhoid fever: present status. Bulletin of the World Health Organization 1994; 72: 957-71.
2. Gotuzzo E, Frisancho O, Sanchez J, Liendo G, Carillo C, Black RE, Morris JG. Association between the acquired immunodeficiency syndrome and infection with Salmonella typhi or Salmonella paratyphi in an endemic typhoid area. Archives of Internal Medicine 1991; 151: 381-2.

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