BIOGENIX
INC. PVT. LTD.

Typhoid IgG/IgM Rapid Test

【Intended Use】

TheBiogenix typhoid IgG/IgM rapid test is a lateral flow immunoassay for the detection and differentiation of IgG and IgM anti-Salmonella typhi(S.typhi) and paratyphi in human serum,plasma or wholeblood.

This device is intended to be usedby professionals as a screening test and as an aidin the diagnosis of infection with S.typhi and paratyphi. Any reactive specimen with the Biogenix typhoid rapid test IgG/IgM must be confirmed with alternative testing method(s).

【Principle】

The Biogenix typhoid IgG/IgM rapid test is a lateralflow chromatographic immunoassay.The test cassette consistsof:1) a burgundy colored conjugate pad containin grecombinant H antigen and O antigen conjugated with colloidal gold (HO conjugates)and rabbit IgG-gold conjugates,2) anitrocellulose membrane strip containing two test lines(G and M lines) and a control line (C line).The Mlineis 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 goatanti 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 specimen, will bind to the HO conjugates.The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody form in gaburgundy colored M line,indicating a S.typhi or paratyphi IgM positive test result. IgG antibodies if present in the specimen will bind to the HO conjugates.The immunocomplex is then captured by the pre-coated reagent son the membrane for minga burgundy colored G line,indicating an S.typhi or paratyphi IgG positive test result.

Absence of any test lines (M and G) suggests a negative result.The test contains an internal control (C line) which should exhibita burgundy colored line goat anti-rabbitIgG/rabbit IgG gold conjugate immuno complex regardless of color development on any of the test lines. If the C line does not develop, the test resultis invalid and the specimen must be retested with another device.

【Components】

1. Sealed foil pouches each containing:
   a.One cassette device
   b.Onedesiccant
2. Plastic droppers
3. Sample diluent
4. Instructions for use

【Storage andstability】

Store at 2℃~30℃ in a dry place and avoid direct sunlight.Donot freeze.It is valid for 24 months from date of manufacturing.

【Specimen collection and preparation】

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

Plasma

Step1:Collect blood specimen in to a lavender,blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer) by veinpuncture.
Step2: Separate the plasma by centrifugation.
Step3: Carefully withdraw the plasma into new pre-labeled tube.

Serum

Step1: Collect blood specimen into a red top collection tube (containing no anti coagulants in Vacutainer) by veinpuncture.
Step2:
Allow the blood to clot.
Step3: Separate the serum by centrifugation.
Step4: Carefully with draw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting.Store specimens at 2°C-8°C if not tested immediately for upto 5 days.Specimens should be frozen at-20°C 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 on result interpretation.

Whole blood

Blood Drops of whole blood can be obtained by either finger tip puncture or veinpuncture.Do not use hemolized blood for testing.

specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

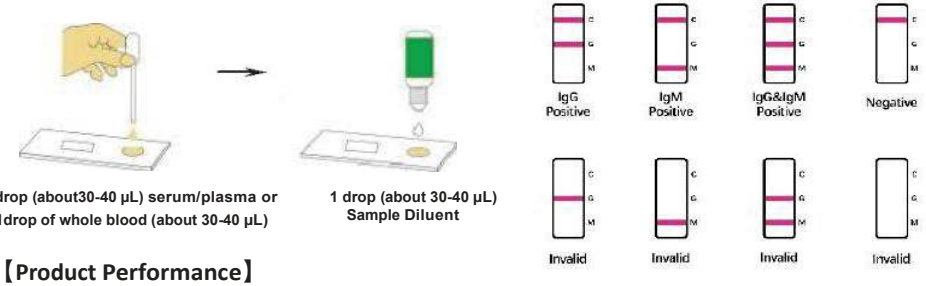
【Test Procedure】

1. Bring the specimen and the test components to room temperature if refrigerated or frozen.Once the specimen is thawed, mix well prior to performing assay.Specimen extraction
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. Label device with the specimen's ID number.
4. Fill the plastic dropper with the specimen.
   Holding the dropper vertically, dispense1 drop (about 30-45 µL)of serum/plasma or 1 drop of wholeblood (about 40-50 µL) into the sample well making sure that there are no air bubbles. Immediately add 1 drop (about 35-50 µL) of Sample Diluent to the sample well.
5. Set up timer. Results can be read in15 minutes.
   Don't read result after 15 minutes.To avoid confusion, discard the test device after interpreting the result.

【Interpretationofresults】

1. Negative:
   If only the C line is present,the absence of any burgundy color in both test lines (M and G) indicates that no anti-S.typhi or paratyphi antibody is detected. The result is non-reactive.
2. Positive:
   - In addition to the presence of the C line,if only the M line is developed,the test indicates the presence of anti-S.typhi or paratyphi IgM.The result is IgM reactive.
   - In addition to the presence of the C line,if only the G line is developed,the test indicates the presence of anti-S.typhi or paratyphi IgG.The result is IgG reactive.
   - In addition to the presence of the C line,if both the M and the G lines are developed,the test indicates the presence of anti-S.typhi or paratyphi IgG and IgM.The result is also reactive.

   Samples with reactive results should beconfirmed with alternative testing method(s) and clinical Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a positived etermination is made.
3. Invalid:
   If no C line is developed,the assay is invalid regardless of any burgundy color in the test lines as indicated below. Repeat the assay with a new device.



1drop (about30-40 μL) serum/plasma or 1drop of whole blood (about 30-40 μL)

1 drop (about 30-40 μL) Sample Diluent

【Product Performance】

1. **Clinical Performance For IgM Test**

A total of 234 samples from susceptible subjects we retested by the Biogenix typhoid IgG/IgM rapid test and by a commercial S.typhi IgM EIA.Comparison for all subjects is shown in the following table:

	BiogenixTyphoid IgG/IgMRapidTest		
IgMEIA	**Positive**	**Negative**	**Total**
Positive	31	3	34
Negative	2	198	200
Total	33	201	234

Relative Sensitivity: 91.2%,Relative Specificity: 99.0%,OverallAgreement: 97.9%

2.**Clinical Performance For IgG Test**

A total of 214 samples from susceptible subjects were tested by the Biogenix typhoid IgG/IgM rapid test and by a commercial S.typhi IgG EIA kit.Comparison for all subjects is shown in the following table:

	BiogenixTyphoid IgG/IgMRapidTest		
IgGEIA	**Positive**	**Negative**	**Total**
Positive	13	1	14
Negative	2	198	200
Total	15	199	214

Relative Sensitivity: 92.9%, RelativeSpecificity: 99.0%, OverallAgreement: 98.5%

【Precautions】

1. This package insert must be read completely before performing the test. Failure to follow the insert may lead to 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 (15-30°C) before use.
5. The testing results should be read within15 minutes after a specimen is applied to the sample well. Reading result after15 minutes may give erroneous results.

【Limitation ofthetest】

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to S.typhi or paratyphi in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Biogenix typhoid IgG/IgM rapid test is limited to the qualitative detection of antibodies to*S. typhi* or *paratyphi* in human serum, plasma or wholeblood.The intensity of the testline does not have a line arcorrelation with the antibody titerin the specimen.
3. An on reactive result for an individual subject indicates absence of detectable anti-*S. typhi* or *paratyphi* antibodies.However, a nonreactive test result does not preclude the possibility of exposure to *S.typhi* or *paratyphi*.
4. An on reactive result can occur if the quantity of anti-S.typhi or paratyphi antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected

【WASTE MANAGEMENT OR DISPOSABLE】

The contents of RDTscan be divided into:

Infectious waste:
- sharps (lancets,needles,scalpelblades)
- blood collection devices(tubes,straws,and loops);gloves;swabs;and cotton
- used cassettes.

Non-infectious waste(Recyclable):
- packaging materials,desiccant,buffer,and unused or unusable RDTs.

** *You must collect and dispose each type of waste in separate containers as per your waste management policies.*

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