Typhoid Ab FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-TPH-001

A Fluorescence Immunoassay for the qualitative detection of IgG and IgM antibodies to Salmonella typhi (S. typhi) in human whole blood, serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Typhoid Ab FIA Rapid Test Device is based on Fluorescence Immunoassay for the qualitative detection of IgG and IgM antibodies to *Salmonella typhi (S. typhi)* in whole blood, serum, or plasma. This test is used as an aid in the diagnosis of *S. typhi* infections.

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.[1] Patients who are infected with HIV are at significantly increased risk of clinical infection with *S. typhi*.[2] Evidence of *H. pylori* infection also presents an increased risk of acquiring typhoid fever. 1-5% of patients become chronic carrier harbouring *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 cannot afford to perform this complicated and time-consuming procedure, Widal test (also referred as Weil-Felix Test) is used to facilitate the diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test.[3,4]

PRINCIPLE

The Typhoid Ab FIA Rapid Test Device detects antibodies (IgG and IgM) to *Salmonella typhi* (*S. typhi*) in human whole blood, serum or plasma specimen based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains antibodies (IgG and IgM) of *S.typhi*, it attaches to the fluorescent microspheres conjugated *Salmonella typhi* antigens. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane. The concentration of *Salmonella typhi* antibodies *S. typhi* (IgG and IgM) in the sample correlates with the fluorescence signal intensity captured on the T line, The testing result of *S. typhi* antibodies (IgG and IgM) will be calculated by the Biopanda Fluorescence Immunoassay Device and displayed on screen.

REAGENTS

The test contains *S. typhi* antigen conjugated particles and anti-human IgG/IgM antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda Typhoid Ab FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 25 x foil wrapped Typhoid Ab test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (Typhoid Ab)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

For Venipuncture Specimens

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K2, Heparin sodium, Sodium citrate, and Oxalate potassium can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum specimens.

For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 15 minutes. *Quick* Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to users' requirements, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. Follow the appropriate steps below for the chosen specimen type:
   a. **For venipuncture whole blood/serum/plasma specimens:**
      i. Pipette **20 µl of whole blood/serum/plasma** into the specimen well.
      ii. After the sample has absorbed into the specimen well (about 5-10 seconds), add **2 drops of buffer** (about 80 µL) into the specimen well. Start the timer at the same time.
   b. **For finger-prick whole blood specimens:**
      i. Wash hands with soap and warm water or clean finger with an alcohol pad. Allow to dry.
      ii. Massage the hand without touching the puncture site by applying pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.
      iii. Use a sterile lancet to puncture the skin. Wipe away the first sign of blood.
      iv. Gently apply pressure from palm to the pricked finger so a rounded drop of blood forms over the puncture site.
      v. Using the provided capillary dropper and ensuring the dropper is level, touch the open end to the rounded drop of blood without

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squeezing the dropper bulb. The dropper will automatically collect the correct volume of blood (approx. 20 µl).

vi. Dispense the whole blood specimen into the specimen well by squeezing the dropper bulb.

vii. After the sample has absorbed into the specimen well (about 5-10 seconds), add **2 drops of buffer** (about 80 µL) into the specimen well. Start the timer at the same time.

5. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The results of tests for Typhoid Ab is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Reference Value. This Value is calculated that a measured signal is divided by an appropriate cutoff value.

- Test results of a Value ≥ 1.00 COI are considered positive for *S. typhi* IgG and/or IgM.

- Test results of a Value < 1.00 COI are considered negative for *S. typhi* IgG and/or IgM.

The Reference Value is not a quantitative value or the rate of IgG or IgM antibodies to *S. typhi* concentration. This is only a qualitative test.

QUALITY CONTROL

Each Biopanda Typhoid Ab FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Typhoid Ab FIA Rapid Test Device is for *in vitro* diagnostic use only. The test should be used for the detection of *S. typhi* IgG/IgM antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *S. typhi* IgG/IgM antibodies can be determined by this qualitative test.
2. The Typhoid Ab FIA Rapid Test Device will only indicate the presence of *S. typhi* IgG/IgM antibodies in the specimen and should not be used as sole criteria for the diagnosis of Typhoid *disease*.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *S. typhi* IgG/IgM infection.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

A clinical evaluation was conducted comparing the results obtained using the Typhoid Ab FIA Rapid Test Device to Typhoid IgG/IgM ELISA Testing. The results are tabulated as below:

IgM Results

Method		ELISA		Total Results
Typhoid Ab FIA Rapid Test Device	Results	Positive	Negative	
	Positive	63	2	65
	Negative	2	298	300
Total results		65	300	365

Sensitivity: 96.9% (95%CI*: 89.3%~99.6%)
Specificity: 99.3% (95%CI*: 97.6%~99.9%)
Accuracy: 98.9% (95%CI*: 97.2%~99.7%) *Confidence Intervals

IgG Results

Method		ELISA		Total Results
Typhoid Ab FIA Rapid Test Device	Results	Positive	Negative	
	Positive	58	1	59
	Negative	2	299	301
Total results		60	300	360

Sensitivity: 96.7% (95%CI*: 88.5%~99.6%)
Specificity: 99.7% (95%CI*: 98.2%~99.9%)
Accuracy: 99.2% (95%CI*: 97.6%~99.8%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of the 3 specimens: a negative, a low positive, and a high positive. These test results were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive, and a high positive. Three different lots of the Typhoid Ab FIA Rapid Test Device have been tested over a 3-days period. These test results were correctly identified >99% of the time.

Cross-reactivity

The Typhoid Ab FIA Rapid Test Device has been tested for HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, HCV, HIV, *H.Pylori*, CMV, Rubella and Toxo positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Typhoid negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2 g/dL
Bilirubin: 1g/dL	Oxalic Acid: 600mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCES

1. Ivanoff BN, Leivne MM, and 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. *Salmonella typhi* or *Salmonella paratyphi* in an endemic typhoid area. Archives of Internal Medicine 1991;151:381-2
3. Clegg A, Passey M, Omena MK,et al. Re-evaluation of the Widal agglutination test in response to the changing pattern of typhoid fever in the highlands of Papua New Guinea. Acta Tropica 1994;57:255-63
4. Pang T. False positive Wiadal test I non-typhoid Salmonella infection. Southeast Asian Journal of Tropical Medicine and Public Health 1989;20:163-4

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's Typhoid Ab FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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