Biopanda Reagents

Product Insert: RAPG-TPH-003

CE

Typhoid Antigen Rapid Test
(*Salmonella typhi*)
Catalogue Number: RAPG-TPH-003

TEST KIT DESCRIPTION
The Biopanda Typhoid Antigen Rapid Test (*Salmonella typhi*) qualitatively detects for the presence of *Salmonella typhi* antigen in faeces. This test applies lateral flow immuno-chromatography and is for professional *in vitro* diagnostic use.

PRINCIPLE
The Typhoid Antigen (*S. typhi)* Rapid Test is a qualitative, lateral flow immunoassay for the detection of *S. typhi* antigen in human faeces. In this test, the membrane is pre-coated with anti-*S. typhi* antibodies on the test line region of the strip. During testing, the specimen reacts with the particle coated with anti-*S. typhi* antibodies. The mixture migrates laterally on the membrane by capillary action to react with anti-*S. typhi* antibodies on the membrane and generate a coloured line. The presence of this coloured line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS
- 10 x foil wrapped test cassettes with desiccant.
- 10 x faecal collection device containing buffer
- 1 x product insert

STORAGE AND STABILITY
Store the kit between 2-30°C and ensure the kits are not frozen or stored in direct sunlight. The test is valid until the expiration date printed on the foil wrapping.

PRECAUTIONS
Follow these instructions for the best results:
- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not use test if pouch is damaged.
- Ensure all components of the kit reach room temperature (15-30°C) before testing.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

SAMPLE COLLECTION AND PREPARATION
- The faeces specimen must be collected in a clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

1.Collect sufficient quantity of faeces (1-2 ml or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

2.**To process faecal specimens:**

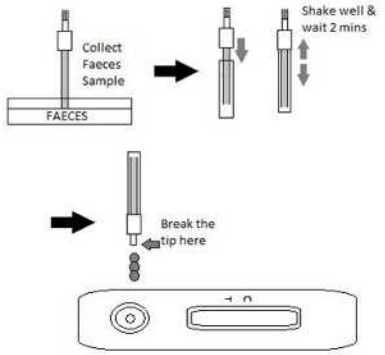
For Solid Specimens: Unscrew the cap of the specimen collection tube then randomly stab the specimen collection applicator into the faecal specimen in at least 3 different sites to collect approximately 50 mg of faeces (equivalent to 1/4 of a pea). Do not scoop the faecal specimen.

For Liquid Specimens: Hold the dropper vertically, aspirate faecal specimens, and then transfer 2 drops (approximately 100 µl) into the specimen collection tube containing the extraction buffer.

Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube to sit for 2 minutes.

TEST PROCEDURE
1. Remove the cassette from its foil wrapping and place on a flat, clean surface. Use immediately.
2. Holding the sample collection device upright, carefully break off the tip of collection device.
3. Squeeze 3 drops (approx. 120 µl) of the sample solution into the specimen well of the cassette, as in the illustration. Avoid air bubbles.
4. Read the test results at 5 minutes. Results read after 15 minutes are considered invalid.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 120 µl of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.

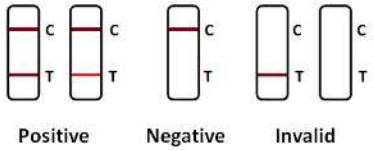


TEST RESULTS
Positive Results: Two lines appear. One coloured line should appear in the control line region (C) and another coloured line should appear in the test line region (T).

***NOTE:** The intensity of the colour in the test line region (T) will vary depending on the concentration of *S.typhi* antigen present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

Negative Results: One coloured line appears in the control line region(C). No line appears in the test line region (T).

Invalid Results: Control line fails to appear.



LIMITATIONS
1.The Biopanda Typhoid Antigen Rapid Test (*Salmonella typhi*) is for *in vitro* diagnostic use only. The test should be used for the detection of *S. typhi* Ag in faecal specimens only. Neither the quantitative value nor the rate of increase in *S. typhi* Ag

concentration can be determined by this qualitative test.

2. The Biopanda Typhoid Antigen Rapid Test (*Salmonella typhi*) Rapid test will only indicate the presence of *S. typhi* Ag in the specimen.
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* infection.
5. Use caution using this test if patients are taking antibiotics as certain antibiotics may decrease *S. typhi* concentration below the detectable levels of this test.

VALIDATION STUDIES

SENSITIVITY AND SPECIFICITY

The Biopanda Typhoid Antigen Rapid Test (*Salmonella typhi*) has been compared with other lateral flow rapid tests on the market, demonstrating an overall accuracy of 98.3%. The test has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity is 96.2% and the specificity is 99.2% relative to the other rapid test.

Method		Other Rapid Test		Total Result
Biopanda *S. typhi* Ag Rapid Test	Results	Positive	Negative	
	Positive	51	1	52
	Negative	2	125	127
Total Result		53	126	179

Relative Sensitivity: 96.2% (95%CI*: 87.0%-99.5%) *Confidence Interval
Relative Specificity: 99.2% (95%CI*: 95.7%-100%)
Accuracy: 98.3% (95%CI*: 95.2%-99.7%)

PRECISION

INTRA-ASSAY

Within-run precision has been determined by using 15 replicates of four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. The specimens were correctly identified >99% of the time.

INTER-ASSAY

Between-run precision has been determined by 15 independent assays on the same four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. Three different lots of the Biopanda Typhoid Antigen Rapid Test (*Salmonella typhi*) have been tested using these specimens. The specimens were correctly identified >99% of the time.

CROSS-REACTIVITY

Cross reactivity with following organisms has been studied at 1.0E+09organisms/ml. The following organisms were found negative when tested with the Biopanda Typhoid Antigen Rapid Test (*Salmonella typhi*):

Acinetobacter calcoaceticus	Acinetobacter spp	
Branhamella catarrhalis	Candida albicans	
Chlamydia trachomatis	Enterococcus faecium	
E.coli	Enterococcus faecalis	
Gardnerella vaginalis	Group A Streptococcus	
Group B Streptococcus	Group C Streptococcus	
Hemophilus influenza	Klebsiella pneumonia	
Neisseria gonorrhea	Neisseria meningitides	
Proteus mirabilis	Proteus vulgaris	
Pseudomonas aeruginosa	Rotavirus	
Helicobacter Pylori	Staphylococcus aureus	Adenovirus

REFERENCES

1. Ivanoff B. Typhoid fever, global situation and WHO recommendations. Southeast Asia J. Trop. Med. Public Health, 1995, 26:supp2 1-6
2. Parry CM, Hien TT Dougan G et al., Typhoid fever, N. Eng. J. Med. 2002, 347:1770-82.

Thank you for purchasing Biopanda's Typhoid Ag (Salmonella typhi) Rapid Test kit. Please read this manual carefully before operating to ensure proper use.

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