H. Pylori Ag FIA Rapid Test Device

Catalogue No.: FI2-HPAG-001

(Human Faeces)

A rapid test for the quantitative detection of H. pylori antigens in human faecal specimens with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda H. pylori Ag FIA Rapid Test Device is intended for *in vitro* quantitative detection of Helicobacter pylori antigens in human faecal specimens.

SUMMARY

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.[1,2] Both invasive and non-invasive methods are used to diagnose H. pylori infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.[3] A very common approach to the diagnosis of H. pylori infection is the serological identification of specific antibodies in infected patients. The main limitation of serology test is the inability to distinguish current and past infections. Antibodies may be present in the patient's serum long after eradication of the organisms.[4] HpSA (H. pylori Stool Antigen) testing is gaining popularity for diagnosis of H. pylori infection and also for monitoring the efficacy of the treatment of H. pylori infection. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with H. pylori.[5]

The H. pylori Ag FIA Rapid Test Device is a Fluorescence Immunoassay for the quantitative detection of H. pylori antigens in human faecal specimens. The test utilizes antibodies specific for H. pylori antigens to selectively detect H. pylori antigens in human faecal specimens.

PRINCIPLE

The Biopanda H. pylori Ag FIA Rapid Test Device detects H. pylori antigen based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. The H. pylori antigen in the specimen will be combined with the anti-H.pylori antibody that has been conjugated with fluorescent microspheres and the combination will be captured by another anti-H.pylori antibody coated on the membrane. The more H. pylori Antigen in the specimen, the more fluorescent microspheres captured on the membrane. The concentration of H. pylori Antigen in the specimen is positively related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of H. pylori Antigen in the specimen can be calculated and reported by the Fluorescence Immunoassay Device (BR-FIA-2000).

REAGENTS

The test includes anti-H.pylori antibody-1 coated particles and anti-H.pylori antibody-2 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. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. 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.
6. Do not interchange or mix reagents or ID cards from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda H. pylori Ag FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) 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

Materials Provided:

- 25 x foil wrapped H. pylori Ag Rapid Test Device
- 25 x Specimen collection tubes with buffer solution
- 1 x ID card (H. pylori Ag)
- Package Insert

Materials required but not provided:

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

SPECIMEN COLLECTION AND PREPARATION

Specimen Collection

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).

Specimen Storage and Shipping

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. If specimens are to be shipped, these should be packed in compliance with local regulations covering the transportation of etiological agents.

Preparation

Before performing the test, please bring the specimen to room temperature (15-30 °C). Frozen specimens must be completely thawed and mixed well prior to testing.

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

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. 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:

Pipette **80 µL** of faeces into the specimen collection tube containing the buffer.

Tighten the cap onto the specimen collection tube and then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Let the tube sit for 2 minutes.

4. Remove the test Device from the sealed foil pouch and place it on a clean, level surface. The Device should be used within one hour of opening.
5. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and **discard 2 drops of the extracted specimen (approximately 80 µL),** then transfer **2 full drops of the extracted specimen (approximately 80 µL)** to the specimen well of the test device and then start the timer. Avoid trapping air bubbles in the specimen well.
6. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The test result of the H. pylori Ag FIA Rapid Test Device is calculated by the Fluorescence Immunoassay Device (BR-FIA-2000) and displayed on the screen with concentration range of 2~1500 ng/mL.
Reference range: <2.5 ng/mL.

QUALITY CONTROL

Each H. pylori Ag FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient specimen 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 "N/A" message on the Analyser. 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 OF THE TEST

1. The H. pylori FIA Ag Rapid Test Device should be used only with the Fluorescence Immunoassay Device (BR-FIA-2000).
2. The test should preferably be performed on freshly collected specimens. For stored specimens, please refer to specimen storage.
3. The H. pylori FIA Ag Rapid Test Device is for professional *in vitro* diagnostic use and for the quantitative detection of H. pylori Antigen.
4. The test may yield low results due to H. pylori Antigen epitopes being covered by some unknown components. Low results may also be obtained due to instability or degradation of H. pylori Antigen with time and temperature.
5. Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components as well as presence of interfering substances in the test specimens.
6. The H. pylori FIA Ag Rapid Test Device will only indicate the presence of H. pylori Antigen in the specimen and should not be used as the sole criteria for clinical result.
7. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
8. The results obtained on the Biopanda Fluorescence Immunoassay Device are only for the concentration of H. pylori Antigen. It should not be used as the sole criterion for treatment decisions. If the result is abnormal, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
< 2.5 ng/mL	Negative result
≥ 2.5 ng/mL	Positive result

Each laboratory should determine the applicability of the reference range through experiments and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
   The test deviation is ≤ ±20%.
2. **Assay Range**
   Assay Range is 2~1500 ng/mL.
3. **Precision**
   Intra-lot precision
   Within-run precision has been determined by using 10 replicates of 2 different concentration of H. Pylori Antigen control. C.V. is ≤ 15%.
   Inter-lot precision
   Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentration of H. Pylori Antigen control. C.V. is ≤20%.
4. **Method comparison**
   The H. pylori Ag FIA Rapid Test Device has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the H. pylori Ag FIA Rapid Test Device is 98.00% and the specificity is 96.00% relative to Endoscope-based methods.

Method		Endoscope-based methods		Total Result
H. pylori Ag FIA Rapid Test Device	Results	Positive	Negative	
	Positive	49	2	51
	Negative	1	48	19
Total Result		50	50	100
Relative Sensitivity		98.00% (95%CI*: 89.35%~99.95%)		
Relative Specificity		96.00% (95%CI*: 86.29%~99.51%)		
Accuracy		97.00% (95%CI*: 91.48%~99.38%)		

REFERENCES

1. Marshall, BJ, McGechie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacter infection and gastro duodenal disease. Med. J. Australia. (1985), 149: 439-444.
2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.(1990), 322: 909-916.
3. Hazell, SL, et al. Campylobacter pyloridis and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. Amer. J. Gastroenterology. (1987), 82(4): 292-296.
4. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am j. Med. 1996; 100:35S-41S.
5. Anand BS, Raed AK, Malaty HM, et al. Loe point prevalence of peptic ulcer in normal individual with Helicobacter pylori infection. Am J Gastroenterol. 1996,91:1112-1115.

SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test	IVD	*in vitro* diagnostic medical device
	Consult instructions for use	LOT	Batch code
	Storage temperature	Σ	Contains sufficient for <*n*> tests
REF	Catalogue number		Do not use if package is damaged

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

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