

Infection

AFIAS
H. pylori SA

INTENDED USE

AFIAS H. pylori SA is a fluorescence immunoassay (FIA) for the qualitative determination of *Helicobacter pylori* Stool Antigen (H. pylori SA) in human feces. It is useful as an aid in the diagnosis of H. pylori infection and to demonstrate loss of H. pylori antigen following treatment.

For *in vitro* diagnostic use only.

INTRODUCTION

Helicobacter pylori, previously *Campylobacter pylori*, is a gram-negative, microaerophilic bacterium found usually in the stomach. It was present in a person with chronic gastritis and gastric ulcers conditions. It is also linked to the development of duodenal ulcers and stomach cancer. More than 50% of the world's population harbor H. pylori in their upper gastrointestinal tract. Individuals infected with H. pylori have a 10 to 20% lifetime risk of developing peptic ulcers and a 1 to 2% risk of acquiring stomach cancer.

There are several ways to test H. pylori infection. H. pylori infection can be tested noninvasively with a blood antibody test, stool antigen test or the carbon urea breath test.

The **AFIAS H. pylori SA** is an immunoassay for the detection of H. pylori in stool sample.

PRINCIPLE

The test uses a sandwich immunodetection method. The detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized antibodies on a test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by the instrument for AFIAS tests to show H. pylori antigen concentration in the sample.

COMPONENTS

AFIAS H. pylori SA consists of ‘cartridges’ and ‘extraction buffer tubes’.

- Each sealed aluminum pouch contains two cartridges.
- Each cartridge packaged in an aluminum pouch has two components including a cartridge part and detector part.
- The cartridge part contains the membrane called a test strip which has anti-H. pylori IgG at the test line, and rabbit IgG at the control line.
- The detector part has 2 granules containing anti-H. pylori fluorescence conjugate, anti-rabbit IgG-fluorescence conjugate and sodium azide as a preservative in phosphate buffer.
- The extraction buffer contains sodium azide as a preservative in Tris buffer. It is pre-dispensed in extraction buffer tubes. All extraction buffer tubes are packed in a box.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions and procedures described in this ‘Instructions for use’.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, extraction buffer tube and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect test result(s).
- Do not reuse cartridges or extraction buffer tubes. A cartridge should be used for testing one sample only. An extraction buffer tube should be used for processing of one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations.
- If test components and/or sample are stored in refrigerator, then allow cartridge, extraction buffer tube to be at room temperature for approximately 30 minutes before use.
- The instrument for AFIAS tests may generate slight vibration during use.
- Used cartridges, extraction buffer tube and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The cartridge and extraction buffer tube contain sodium azide (NaN₃), and it may cause certain health issues like convulsions, low blood pressure, low heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- AFIAS H. pylori SA** will provide accurate and reliable results subject to the below conditions.
 - AFIAS H. pylori SA** should be used only in conjunction with the instrument for AFIAS tests.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result(s) due to the non-responsiveness of the antigens to the antibodies which is the most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigens with time and/or temperature may also cause false negative result as it makes the antigens unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician in conjunction with clinical symptoms and other relevant test results.

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 – 30°C	20 months	Unopened
		1 month	Resealed
Extraction buffer tube	2 – 30°C	20 months	Disposable

- Return an unused cartridge to the spare cartridge zipper bag containing the desiccant pack. Reseal along entire edge of zip-seal.

MATERIALS SUPPLIED

REF SMFP-178
Components of **AFIAS H. pylori SA**

- Cartridge box:
 - Cartridge 24
 - Extraction buffer tube 24
 - Pipette tip (zipper bag) 24
 - Spare cartridge zipper bag 1
 - ID chip 1
 - Instructions for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately with **AFIAS H. pylori SA**.

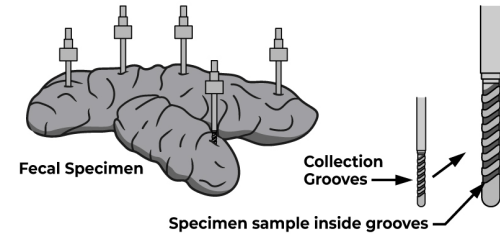
Please contact our sales division for more information.

- Instrument for AFIAS tests**
 - AFIAS-1** **REF** FPRR019
 - AFIAS-3** **REF** FPRR040
 - AFIAS-6** **REF** FPRR020
 - AFIAS-10** **REF** FPRR038
- Boditech H. pylori Ag Control** **REF** CFPO-222

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS H. pylori SA** is human feces.

- Collect the sample feces in a clean and dry container.
- Invert an extraction buffer tube and loosen the cap where the sampling stick (yellow color) is attached.
- Poke the sampling stick into the fecal sample about 5 to 6 times at different sites. Whilst collecting the sample with the sampling stick, make sure to exclude large solid lumps. (In case the fecal matter is in liquid form or when using control, transfer 10 µL of the sample to an extraction buffer tube using a pipette.)



- Return the stick to the extraction buffer tube. Tighten the cap thoroughly and shake the tube vigorously around 10 times so as to disperse the specimen throughout the extraction buffer in the tube.
- Sample (feces) storage periods are as below:
 - Sample (feces) stored at room temperature showed no performance difference for 4 hours.
 - Sample (feces) stored at refrigerator (2~8°C) showed no performance difference for 72 hours.

- Sample (feces) stored at freezer (-20°C) showed no performance difference for 8 weeks.
- The sample mixture storage periods in extraction buffer tube are as below:
 - The sample mixture in an extraction buffer tube stored at room temperature showed no performance difference for 1 hour.
 - The sample mixture in an extraction buffer tube stored at refrigerator (2~8°C) showed no performance difference for 12 hours.
- It is recommended to use the sample mixture in the extraction buffer on the same day after sampling.
- The storage period may vary depending on the condition and type of feces.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen sample.

TEST SETUP

- Check the contents of **AFIAS H. pylori SA**: Cartridges, extraction buffer tubes, pipette tips, an ID chip, a spare cartridge zipper bag and an instructions for use.
- Ensure that the lot number of the cartridge matches that of the extraction buffer tube as well as an ID chip.
- If the sealed cartridge and the extraction buffer tube have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Turn on the instrument for AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the ‘ID chip port’.
- ※ **Please refer to the instrument for AFIAS tests operation manual for complete information and operation instructions.**

TEST PROCEDURE

- **AFIAS-1, AFIAS-3, AFIAS-6**
General mode
- Collect sample using a sampling stick according to the sample collection method described in the ‘sample collection and processing’.
 - Shake the assembled extraction buffer tube about 10 to 15 times.
 - Hold the tube upside down and break off the black tip on the outside of the black cap.
 - Discard 3 drops of reagent onto the paper towel before applying to the cartridge.
 - Squeeze the extraction buffer tube gently to completely fill the sample well.
 - Select the ‘General mode’ in the instrument for AFIAS tests.
 - Insert a cartridge into the cartridge holder.
 - Insert a tip into the tip hole of the cartridge.
 - Tap the ‘Start’ button on the screen.
 - The test result will be displayed on the screen after 12 minutes.
- **AFIAS-10**
Emergency mode – General tip
- The test procedure is same with the ‘General mode 1) – 5)’ for AFIAS-1, AFIAS-3 and AFIAS-6.
 - Insert a cartridge into the cartridge holder.
 - Insert a tip into the tip hole of the cartridge.

- 4) Tap the ‘load’ button of the bay that holds the cartridge with the tip to read the barcode of the cartridge and please confirm the item name written on the cartridge.
- 5) Convert the ‘Emergency mode’ in AFIAS-10.
- 6) Check the tip type (general tip) on the screen.
- 7) Check the sample type (feces) on the screen.
- 8) Tap the ‘Start’ button on the screen.
- 9) The test result will be displayed on the screen after 12 minutes.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculates the test result automatically and displays ‘Positive/Negative’.
- Ancillary value is served in the form of a cut-off index(COI).

Cut-off index (COI)	Result
<1	Negative for H. pylori
≥1	Positive for H. pylori

- Samples are considered equivocal and must be repeated if their COI is within the range 0.1 units above the cut-off.

QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with **AFIAS H. pylori SA**. For more information regarding obtaining the control materials, contact Boditech Med Inc.’s Sales Division for assistance.
(Please refer to the instructions for use of control material.)

PERFORMANCE CHARACTERISTICS

- Analytical Sensitivity

- Limit of Detection (LoD)

0.259 (COI)

- Analytical specificity

- Cross reactivity

Biomolecules listed in the following table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the feces. **AFIAS H. pylori SA** test results did not show any significant cross-reactivity with these biomolecules.

Cross-reactants	Concentration
Candida albicans (ATCC 10231)	4.9X10 ⁷ CFU/mL
Escherichia coli (ATCC 8739)	4.7X10 ⁷ CFU/mL
Pseudomonas aeruginosa (ATCC 9027)	5.9X10 ⁷ CFU/mL
Bacillus subtilis (ATCC 6633)	3.8X10 ⁷ CFU/mL
Clostridium sporogenes (ATCC 11437)	4.2X10 ⁷ PFU/mL
Enterobacter cloacae (ATCC 35030)	9.2X10 ⁸ CFU/mL
Neisseria gonorrhoeae (ATCC 49226)	2.5X10 ⁸ CFU/mL
Neisseria Flavescens (ATCC 13118)	1.6X10 ⁸ CFU/mL
Campylobacter jejuni (ATCC 33560)	3.4X10 ⁷ CFU/mL
Borrelia burgdorferi (ATCC35210)	2.0X10 ⁷ CFU/mL
Proteus morgani (ATCC 25829)	3.5X10 ⁷ CFU/mL
influenza virus infectious A (NIBSC)	83 ug HA /mL
influenza virus infectious B (NIBSC)	29 ug HA/mL

- Interference
- Interferents listed in the following table were added to the test sample at the concentration mentioned below. **AFIAS H. pylori SA** test results did not show any significant interference with these materials.

Interferents	Concentration
Bilirubin	40 mg/dL
Hemoglobin	10 g/dL
Triglycerides	1500 mg/dL
Cholesterol	400 mg/dL
BSA	12 mg/mL
Stearic acid	0.8 mg/mL
Palmitic acid	0.8 mg/mL
Human whole blood	1 %
Leukocytes	1 %
Mucin	0.07 %
barium sulfate	5 %
Tagamet® (Cimetidin)	1 mg/dL
Prilosec® (Omeprazole magnesium)	0.3 mg/dL
Imodium® (Loperamide HCl)	0.1 mg/mL
Mylanta® (Aluminum hydroxide, Magnesium hydroxide, Simethicone)	0.1%
Pepto-Bismol™ (Bismuch subsalicylate)	0.1%
TUMS® (Calcium Carbonate)	5 mg/mL

- Clinical performance

		Comparator A		
		Positive	Negative	Total
AFIAS	Positive	57	1	58
H. pylori	Negative	2	40	42
SA	Total	59	41	100

- Percent positive agreement = 96.6 %
- Percent negative agreement = 97.6 %
- Overall percent agreement = 97.0 %

REFERENCES

- 1.Chang, A. H. and Parsonnet, J. Role of Bacteria in Oncogenesis. Clinical Microbiology Reviews. 2010; 23 (4): 837–857.
- 2.Amieva, Manuel and Peek, Richard M. Pathobiology of Helicobacter pylori–Induced Gastric Cancer. Gastroenterology. 2016; 150 (1): 64–78.
- 3.Blaser MJ Who are we? Indigenous microbes and the ecology of human diseases. EMBO Reports. 2006; 7 (10): 956–60
- 4.Stenström B, Mendis A, Marshall B. Helicobacter pylori—The latest in diagnosis and treatment. Aust Fam Physician. 2008; 37 (8): 608–12.

Note: Please refer to the table below to identify various symbols.

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
	Batch code
	Catalog number
	Caution
	Manufacturer
	Authorized representative of the European Community
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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