BIO TECHNOLOGY bodtech

ichroma™

ichroma™ H. pylori SA

INTENDED USE

ichroma™ H. pylori SA (H. pylori Stool Antigen) is a fluorescence immunoassay (FIA) for the qualitative determination of H. pylori antigen 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 **ichroma™ 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 ichroma™ tests to show H. pylori antigen concentration in the sample.

COMPONENTS

ichroma™ H. pylori SA consists of 'cartridges', 'detector tubes', 'extraction buffer tubes'.

- The cartridge contains the membrane called a test strip which has anti-H. pylori IgG at the test line, and rabbit IgG at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant, and they are further packaged in a box.
- The detector tube has a granule containing anti-H. pylori fluorescence conjugate, anti-rabbit IgG-fluorescence conjugate, sucrose, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffer. All detector tubes are packed in a pouch.
- The extraction buffer tube contains sucrose, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in Tris base buffer. 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, detector tube, 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, detector tubes or extraction buffer tubes. A cartridge should be used for testing one sample only. A detector tube and 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 the 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 sample are stored in refrigerator, then allow cartridge, detector tube, extraction buffer tube and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used cartridges, detector tubes, extraction buffer tubes and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The detector tube and extraction buffer tube contain sodium azide (NaN_3), and they may cause certain health issues like convulsions, low blood pressure and 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.
- **ichroma™ H. pylori SA** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ H. pylori SA** should be used only in conjunction with the instrument for ichroma™ tests.

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 - 30 °C	20 months	Disposable
Detector tube	2 - 30 °C	20 months	Disposable
Extraction buffer tube	2 - 30 °C	20 months	Disposable

- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION 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 antigen 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 antigen with time and/or temperature may also cause false negative result as it makes antigen 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.

MATERIALS SUPPLIED

REF CFPC-81

Components of **ichroma™ H. pylori SA**

- Cartridge box:
  - Cartridge 25
  - Extraction buffer tube 25
  - Detector tube 25
  - ID chip 1
  - Instructions for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ H. pylori SA.**

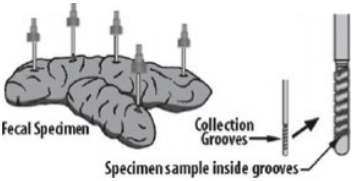
Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FPRR021
  - **ichroma™ III** REF FPRR037
  - **ichroma™- 50** REF FPRR022
  - **ichroma™- 50 PLUS** REF FPRR036
  - **ichroma™ M3** REF FPRR035
- **Printer** REF FPRR007
- **Boditech H. pylori Ag Control** REF CFPO-222

SAMPLE COLLECTION AND PROCESSING

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

- Invert an extraction buffer tube and loosen the cap which is attached a sampling stick (yellow color).
- Insert the sampling stick into the fecal sample five times at different sites. In order to get sampling even in the spirals of the stick and to ensure appropriate specimen to buffer ratio, try to avoid obtaining clumps of fecal matter.



- Return the stick to the extraction buffer tube. Tighten the cap thoroughly and shake the tube vigorously so as to disperse the specimen throughout the extraction buffer in the tube (10 times).

(In case the fecal matter is in liquid form, transfer 10 µL of the sample using a pipette to an extraction buffer tube.)

- If not to be used immediately after addition of fecal sample, extraction buffer tube should be refrigerated but must be analyzed using the test cartridge within 12 hours.
- The collected specimen should be tested as soon as possible, but may be held up to 72 hours at 2-8 °C prior to testing. If testing will be delayed more than this time frame, samples should be frozen at -20 °C.
- Samples stored frozen at -20 °C for 2 months showed no performance difference.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

TEST SETUP

- Check the contents of **ichroma™ H. pylori SA**: Sealed cartridges, extraction buffer tubes, detector tubes, ID chip and instructions for use.
- Ensure that the lot number of the cartridges matches that of the detector tube and the extraction buffer tube as well as an ID chip.
- If the sealed cartridge, the extraction buffer tube and detector 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 ichroma™ tests.
- Insert the ID chip into the 'ID chip port'.
  (Please refer to the Instrument for ichroma™ tests Operation Manual for complete information and operating instructions.)

TEST PROCEDURE

▶ **ichroma™ Reader, ichroma™ II, ichroma™ M3**

Multi test mode

1) Collect sample according to the sample collection method using a sampling stick in the 'sample collection and processing'.
2) Cover the top of the extraction buffer tube with absorbent paper to avoid a splatter.
3) Break off the black tip on the outside of the black cap.
4) Discard 3 drops of reagent onto the paper towel before applying the sample to the cartridge.
5) Hold the vial upside down and transfer 4 drops of sample to a detector tube containing granule.
6) Close the lid of the detector tube and mix the sample thoroughly by shaking it about 20 times.
   (The sample mixture must be used immediately. Do not exceed 30 seconds.)
7) Take 75 µL of the sample mixture and dispense it into the sample well of the cartridge.
8) Leave the cartridge at room temperature for 12 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.*
9) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this

purpose.
10) Press the 'Select' or tap the 'Start' button on the instrument for ichroma™ tests to start the scanning process.
11) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
12) Read the test result on the display screen of the instrument for ichroma™ tests.

Single test mode

1) The test procedure is same with 'Multi test mode 1) – 7)'.
2) Insert the sample-loaded cartridge into the holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
3) Press the 'Select' or tap the "Start" button on the instrument for ichroma™ test.
4) The cartridge goes inside the instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 12 minutes.
5) Read the test result on the display screen of the instrument for ichroma™ tests.

▶ **ichroma™ III**

1) The test procedure is same with the 'Single test mode'.

▶ **ichroma™-50, ichroma™-50 PLUS**

1) Insert the tip array in the tip station.
2) Insert the detector tube in the reagent station and cover the reagent station to hold the detector tubes in place.
3) Open the lid of the detector diluent and insert the detector diluent in the diluent station.
4) Insert the cartridge magazine with the cartridges into the magazine station.
5) Insert the sample tube into the blood collection tube rack and load the blood collection tube rack into the sampling station (loading part).
6) Tap the button located in the upper side of the No. of test cartridge region to select the ID chip that you want to use.
7) When the selected cartridge slot is activated, set the number of the detector tube by tapping.
8) Set the number of pipette tips by tapping.
9) Tap the 'Start' button on the left upper of the main screen to start test.

INTERPRETATION OF TEST RESULT

- The instrument for ichroma™ 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 **ichroma™ 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**
  - Cut-off
  The **ichroma™ H. pylori SA** test result indicates 'positive' or 'negative' of a sample defined by the algorithm of ichroma™ reader based on COI (cut-off index).

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

- **Analytical Specificity**
  - Cross-reactivity
  Biomolecules listed in the following table were added to the test sample at concentrations much higher than their normal physiological levels in the blood. **ichroma™ H. pylori SA** test results did not show any significant cross-reactivity with these biomolecules.

No.	Cross-reactivity material
1	Candida albicans (ATCC 10231)
2	Escherichia coli (ATCC 8739)
3	Pseudomonas aeruginosa (ATCC 9027)
4	Bacillus subtilis (ATCC 6633)
5	Clostridium sporogenes (ATCC 11437)
6	Enterobacter cloacae (ATCC 35030)
7	Neisseria gonorrheae (ATCC 49226)
8	Neisseria Flavescens (ATCC 13118)
9	Campylobacter jejuni (ATCC 33560)
10	Borrelia burgdorferi (ATCC35210)
11	Proteus morgani (ATCC 25829)
12	influenza virus infectious A (NIBSC)
13	influenza virus infectious B (NIBSC)

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

No.	Interferent
1	Bilirubin
2	Hemoglobin
3	Triglycerides
4	Cholesterol
5	BSA
6	Stearic acid
7	Palmitic acid
8	Human whole blood
9	Leukocytes

10	Mucin
11	barium sulfate
12	Tagamet® (Cimetidin)
13	Prilosec® (Omeprazole magnesium)
14	Imodium® (Loperamide HCl)
15	Mylanta® (Aluminum hydroxide, Magnesium hydroxide, Simethicone)
16	Pepto-Bismol™ (Bismuch subsalicylate)
17	TUMS® (Calcium Carbonate)

- **Comparability with reference product**

		Comparator A		
		Positive	Negative	Total
ichroma™ H. pylori SA	Positive	102	1	103
	Negative	3	54	57
	Total	105	55	160

- Percent positive agreement = 97.1 %
- Percent negative agreement = 98.2 %
- Overall percent agreement = 97.5 %

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

For technical assistance, please contact:
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