EN REF F-HPY-01

STANDARD F

H. pylori Ag FIA

STANDARD™ F *H. pylori* Ag FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

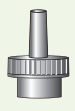
SD BIOSENSOR

KIT CONTENTS

Test device (individually in a foil pouch with desiccant)

Sterile swab

Extraction buffer tube



Filter cap

Instructions for Use

SPECIMEN COLLECTION AND PREPARATION

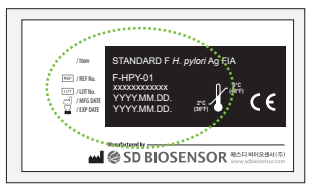
■ Feces

1. Fecal specimen should be collected in a clean and dry container and collected at any time of the day may be used.
2. Urine should be excluded from the fecal specimen.
3. Fresh fecal specimen should be used in this test. Do not use any transport media to store and transport the fecal specimen.

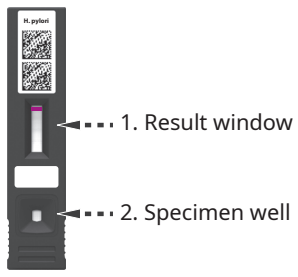
TEST PROCEDURE

■ Preparation

1. Carefully read instructions for using STANDARD F *H. pylori* Ag FIA.
2. Take out the test device in foil pouch.
   * Check the valid expiry date at the back of the foil pouch. Do not use if the expiry date has passed.



Foil pouch



Test device

Desiccant

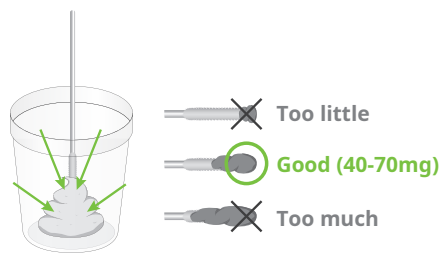
The violet-line on the membrane of unused test device will disappear after use.

Before Use **After Use**

Do not write on the barcode or damage the barcode of the test device.

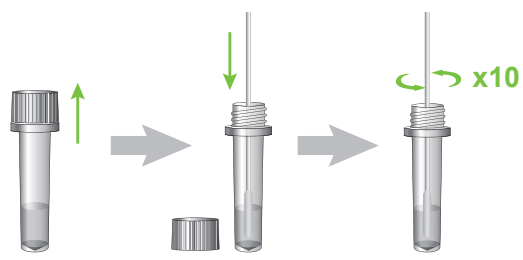
■ Specimen Preparation

1. Poke the 4 different areas of the feces specimen using the sterile swab to collect a portion of feces (about 40-70mg). In case of liquid specimen, soak the sterile swab completely in the liquid fecal specimen.

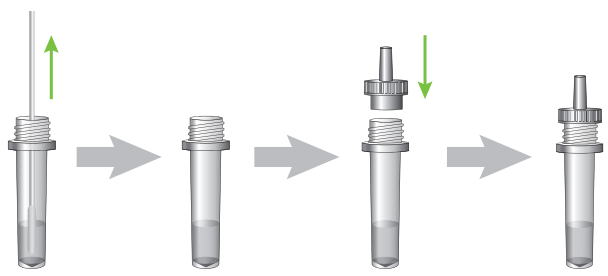


The amount of fecal swab may affect the results. It is required to follow the swab amount of feces as shown in the picture above. Excessive fecal amount may induce a false positive result and slow migration.

2. Take off the top of an Extraction buffer tube and insert the swab into the tube. swirl the swab at least ten times into the Extraction buffer tube to dissolve the specimen.



3. Remove the swab and dispose of the used swab in accordance with your biohazard waste disposal protocol. Tightly press down the filter cap onto the tube.



Do not use the extraction buffer tube without the filter cap. It affects the result value.

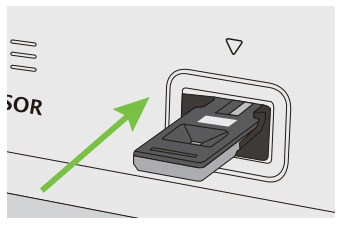
■ Analysis of specimen

'STANDARD TEST' mode — **STANDARD F100, F200 and F2400 analyzer**

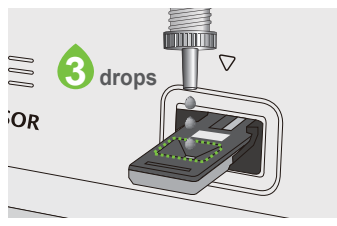
1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write patient information on the label of test device.

STANDARD F2400 analyzer	'Workplace' → 'Run Test' → Insert patient ID and / or operator ID on the analyzer
STANDARD F100 and F200 analyzer	'STANDARD TEST' mode → Insert patient ID and/or operator ID

2. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.



3. Apply 3 drops of mixed specimen to the specimen well in the test device holding the prepared extraction buffer tube upside down.



4. After applying the specimen, immediately press the **'TEST START'** button.

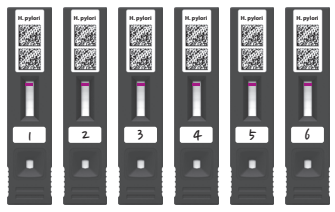
F100 **F200** **F2400**

5. The analyzer will automatically display the test result after 10 minutes.

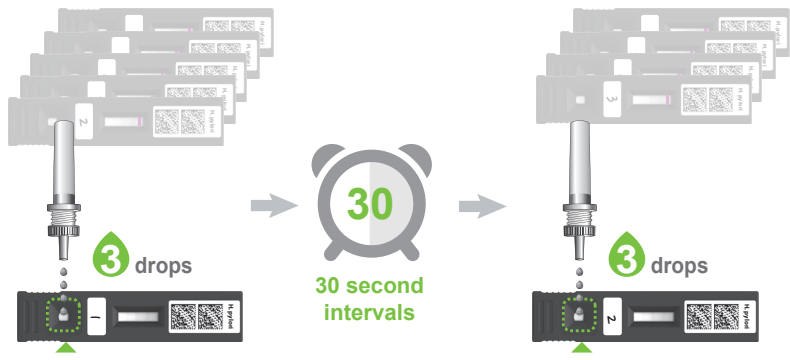
'READ ONLY' mode — **STANDARD F100 and F200 analyzer**

1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write a specimen information on the label of test device.
2. Prepare extracted specimens.

3. Prepare test devices depending on the workload.

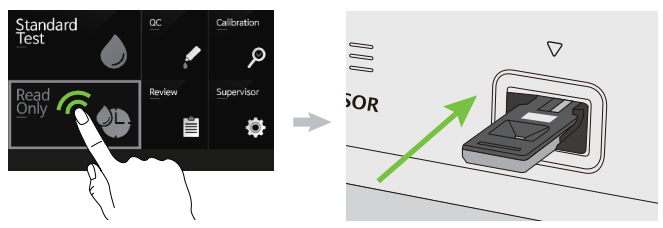


4. Apply 3 drops of extracted specimen into test devices in sequence at about 30 seconds intervals.



5. Incubate the test device for 10 minutes outside of the analyzer.

6. Select the 'Read Only' mode on the screen, and insert test devices in sequence.



7. The analyzer will automatically scan and display the test result immediately.

INTERPRETATION OF TEST RESULTS

■ Interpretation

Result	COI (Cutoff index) value	Interpretation
Positive	COI ≥ 1.0	*H. pylori* Ag positive
Negative	COI < 1.0	*H. pylori* Ag Negative
Invalid	COI value is not displayed	Retest should be performed with a new test device and a new patient specimen

The test result of a specimen is given either as Positive (+) / Pos (+) or Negative (-) / Neg (-) with a COI (cut off index) value. The COI is a numerical representation of the measured fluorescence signal.

EXPLANATION AND SUMMARY

■ Introduction

Helicobacter pylori is a small, spiral-shaped bacterium that lives on the surface of the stomach and duodenum. The organism is very common, infected at least half of the world's population. *H. pylori* infection is associated with the etiology of a variety of gastrointestinal diseases, including non-ulcer dyspepsia, duodenal and gastric ulcer, and active and chronic gastritis. Studies also suggest an association of *H. pylori* infection with stomach cancer; the role of *H. pylori* and the factors involved in the development of these diseases are still under investigation. 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, culture or histologic staining. Noninvasive techniques include the urea breath test, serological methods and Helicobacter pylori stool antigen test. STANDARD F *H. pylori* Ag FIA provides the significantly fast, easy and accurate system to detect the *H. pylori* antigens in the human fecal specimen. It is essential for the reliable clinical diagnosis of *H. pylori* infection and enables supportive treatment decisions.

■ Intended use

STANDARD F *H. pylori* Ag FIA is a qualitative immunoassay to detect *H. pylori* Ag in the human fecal specimen. The test is for in vitro diagnostic use and is intended as an aid to early diagnosis of *H. pylori* Ag infection. This is intended for professional use, only for an initial screening test.

■ Test principle

STANDARD F *H. pylori* Ag FIA is based on the immunofluorescence technology with STANDARD F Analyzer manufactured by SD BIOSENSOR to measure *H. pylori* antigen in human fecal specimens. The specimen from human fecal should be processed for the preparation using the components of the STANDARD F *H. pylori* Ag FIA. After applying the specimen mixture to the test device, the complex will be formed on the membrane as the result of the antigen-antibody reaction. The intensity of fluorescence light produced on the membrane. STANDARD F Analyzers can analyze the *H. pylori* antigen of the clinical specimen based on a pre-programmed algorithms and display the test result on the screen.

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Carefully follow the instructions and procedures described in this instructions while testing.
3. STANDARD F *H. pylori* Ag FIA should be performed with STANDARD F Analyzers.
4. STANDARD F *H. pylori* Ag FIA test device should remain in its original sealed pouch until ready to use. Do not use if the pouch is damaged or the seal is broken.
5. STANDARD F *H. pylori* Ag FIA is single use only. Do not re-use it.
6. Do not use an artificial materials as specimen.
7. Place the analyzer on a flat surface when in use.
8. Wash your hands in warm and soapy water. Rinse well and dry completely before testing.
9. Handle all specimens and materials used as biohazard waste. Laboratory chemicals and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Check the expiration date printed on the pouch, labels or outer package.
11. Do not write on the barcode or damage the barcode on the test device.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. Test results must be considered with other clinical data available to the physician.
3. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
4. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
5. The interference may occur if blood streptavidin concentration is very high.
6. This test is not affected by jaundice (bilirubin ≤ 257 umol/L) and biotin (≤300 ng/ml).
7. In the case of patients receiving high doses of biotin (>5 mg/day), specimens should be collected at least 8 hours after the last biotin administration.

QUALITY CONTROL

■ Calibration

The calibration set test of STANDARD F analyzer should be conducted according to the analyzer's manual.

[When to use calibration set]

1. Before using the analyzer for the first time.
2. When you drop the analyzer.
3. Whenever you do not agree with the final result.
4. When you want to check the performance of an analyzer and test device.

[How to use calibration set]

Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.

1. Select the 'Calibration' in main menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 for white calibration, CAL-2 for UV LED calibaration, and CAL-3 for RGB LED calibration in sequence.

STANDARD F analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with test device. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

■ External quality control

Quality control testing should be run to check the performance of STANDARD F *H. pylori* Ag FIA and STANDARD F Analyzers. STANDARD F *H. pylori* Control manufactured by SD BIOSENSOR should be used for quality control testing. Control test should be conducted in accordance with the instructions of STANDARD F *H. pylori* Control. Control test should be run:

- once for each new lot.
- once for each untrained operator.
- as required by test procedures in instructions for use of STANDARD F *H. pylori* Control and in accordance with local, state and federal regulations or accreditation requirements.

BIBLIOGRAPHY

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CE IVD

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or you can also contact us through www.sdbiosensor.com
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REF Reference number | IVD *In vitro* Diagnostics | Consult Instructions for Use | Σ Contains Sufficient for <n> Tests | Caution | Note | Do not re-use. | To indicate the temperature limitations in which the transport package has to be kept and handled. | Use by | LOT Batch code | CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices | Manufacturer | Date of manufacture | Indicate that you should keep the product dry | Keep away from sunlight | Do not use if packaging is damaged