

Read this Instructions For Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Helicobacter pylori antigen kit

Quick Chaser® H. pylori Test plate

[General precautions]

- 1) Do not use this product for other purpose than in vitro diagnosis.
- 2) The diagnosis of *Helicobacter pylori* infection should be comprehensively made not only by the test result of this products, but also in conjunction with the assessment of clinical progress and results of other tests.
- 3) Procedures other than described in this instruction for use are not guaranteed.

[Contents]

- 1) Test plate - 10 tests
 - Mouse monoclonal anti- *Helicobacter pylori* antibodies
 - Colloidal gold conjugated to mouse monoclonal anti- *Helicobacter pylori* antibodies

(Sold separately: Quick Chaser® H. pylori Feces Collection Set)

 - Extraction reagent solution - 10 pieces
 - Instructions for patients (feces collection) - 10 copies
 - Resealable plastic bags (for submission) - 10 pieces

[Intended use]

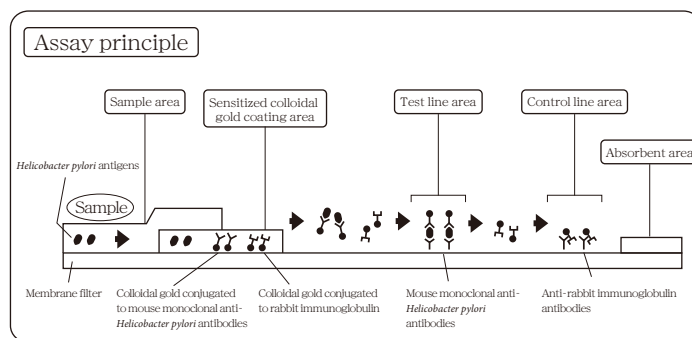
For detection of *Helicobacter pylori* antigen in feces (An aid of diagnosis for *Helicobacter pylori* infection)

[Principle of the test]

“Quick Chaser® H. pylori” is the in-vitro reagent for detection of *Helicobacter pylori* based on Immunochromatographic Assay.

Colloidal gold conjugated to mouse monoclonal anti-*Helicobacter pylori* antibodies and colloidal gold conjugated to rabbit immunoglobulin for control line are coated in sensitized colloidal gold coating area on a membrane filter which is set in test plate. Mouse monoclonal anti-*Helicobacter pylori* antibodies are immobilized in test line area, and anti-rabbit immunoglobulin antibodies are immobilized in the control line area.

If *Helicobacter pylori* antigens are present in the sample, according to the principle of immunochromatography, *Helicobacter pylori* antigens in the sample which migrated from the sample area react with colloidal gold conjugated to mouse monoclonal anti-*Helicobacter pylori* antibodies, and moreover they are caught in the test line area, by reacting with mouse monoclonal anti-*Helicobacter pylori* antibodies. As a result, purple-red line with the colloidal gold, appears in the test line area. At the same time, the colloidal gold conjugated to rabbit immunoglobulin also migrates and is captured by the anti-rabbit immunoglobulin antibodies on the control line area, resulting in the appearance of a purple-red line in control line area regardless of the presence or absence of *Helicobacter pylori* antigens.



[Procedural precautions]

- 1) Use fresh feces for testing.
- 2) Be sure to use “Quick Chaser® H. pylori Feces collection set” which is sold separately when collecting samples.
- 3) Use the collected specimen as soon as possible in accordance with instruction of specimen collection and sample preparation in “Test procedure”. Specimen can be stored refrigerated for up to 72 hours. If the sample cannot be prepared right away or specimen needs to be preserved for a long period of time, store the specimen under -30°C and avoid repeating the freezing and thawing.
- 4) Test a prepared sample promptly. If you must preserve the sample, keep under 30°C for up to 7 days, or refrigerate if exceed 7 days. When using the preserved sample, return to $15\sim 30^{\circ}\text{C}$ before use.
- 5) Bring test plate and extraction reagent solution to $15\sim 30^{\circ}\text{C}$ prior to testing.
- 6) When feces are precipitated in the specimen container at the time of testing, stir thoroughly until the feces are suspended evenly.
- 7) Add fixed volume (3 drops) to the center of sample area from dropping part, about 10mm away from the sample area so as to make droplets. In case of adding other than fixed volume, an accurate reaction may not be performed.
- 8) Be sure to keep interpretation time as it may cause false-negative or false-positive.
- 9) Interfering substances and medications
The following substances and blood did not interfere with the performance of this product at the concentration listed below:

Barium sulfate	0.25%
Mucins	0.25%
Stearic Acid	0.25%
Palmitic acid	0.25%
Blood	10%

10) Cross reactivity

Cross reactivity with the following bacteria were not observed. *Bacteroides vulgatus*, *Bifidobacterium adolescentis*, *Bifidobacterium infantis*, *Bifidobacterium breve*, *Campylobacter jejuni*, *Candida albicans*, *Citrobacter freundii*, *Clostridium perfringens*, *Escherichia coli*, *Enterobacter cloacae*, *Enterococcus faecalis*, *Helicobacter felis*, *Helicobacter hepaticus*, *Helicobacter mustelae*, *Helicobacter cinaedi*, *Klebsiella pneumoniae*, *Lactobacillus gasseri*, *Lactobacillus Lactis*, *Lactobacillus reuteri*, *Listeria monocytogenes*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*

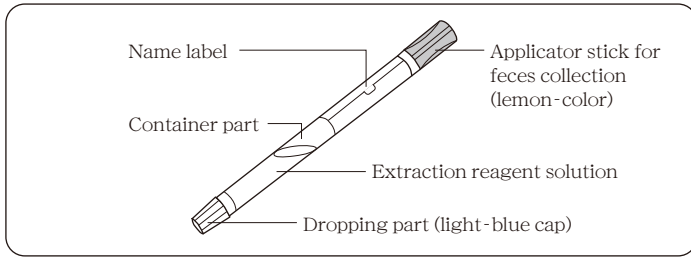
[Test procedure]

●Feces collection and sample preparation

1) Preparation of feces collection

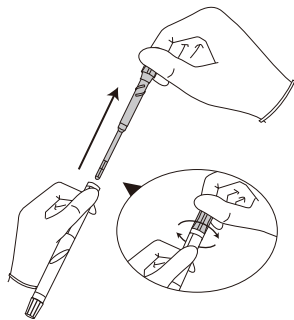
Use “Quick Chaser® H. pylori Feces collection set” which is sold separately.

●Details of feces collection container



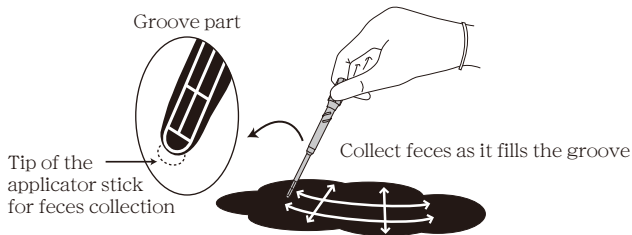
●Feces collection and sample preparation

① Remove lemon-color applicator stick for feces collection by lightly turning it counterclockwise.



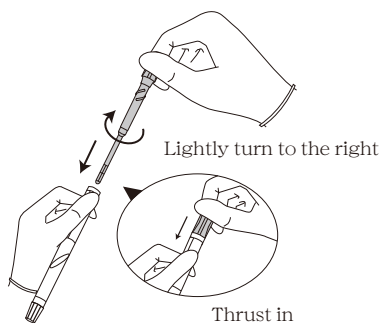
※Do not remove light-blue cap at this time. Do not tilt the portion of the opening sideways or downward while the lemon-color applicator stick for feces collection is removed, as it may cause specimen diluent in the specimen container to spill out.

② Scrape the feces evenly with groove part of an applicator stick for feces collection.



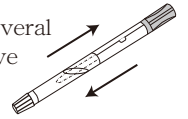
※Depending on the nature of the feces, it may not be collected correctly, so collect as much as possible to fill the groove. Remove the feces attached to the tip of the applicator stick for feces collection. Do not collect directly from the rectum with an applicator stick for feces collection.

③ Put the applicator stick for feces collection back into the container by lightly turning it to the right and thrusting in.

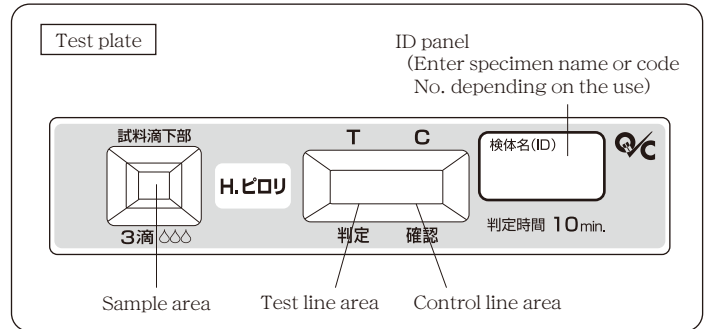


※Lightly turn the applicator stick for feces collection to the right and thrust in firmly.

④ Shake the specimen container vigorously several times to dissolve fecal specimen in the groove to provide a good homogenous specimen.



●Details of test plate



●Test procedure

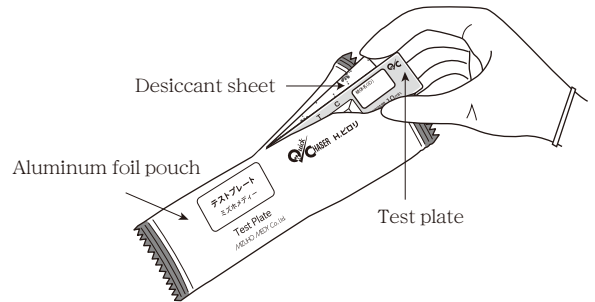
1) Sample preparation

Test plate : No prior preparation required

2) Test procedure

① Remove test plate from aluminum foil pouch.

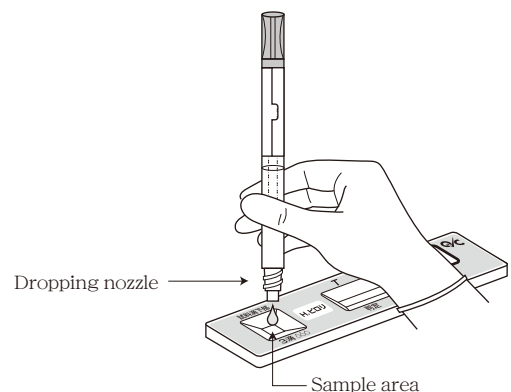
Discard desiccant sheet included in aluminum foil pouch.



② Loosen and remove the light-blue cap on the feces collection container. Discard first 1 or 2 drops.

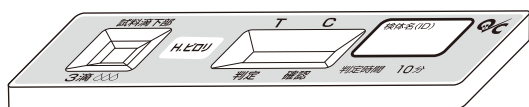


③ Add 3 drops (approx. 110 μL) of prepared sample vertically to sample area of test plate from the feces collection container, avoiding contact of tip of dropping nozzle with sample area.



④ Leave to react at 15~30 °C.

Visually interpret test result by lines in the test line area and control line area after 3~10 minutes.

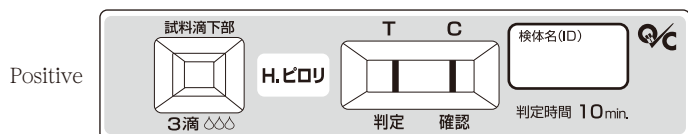


[Interpretation]

Interpret by presence of red-purple lines in test line area and control line area.

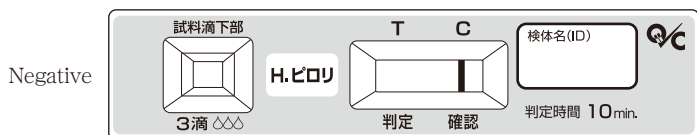
《Positive》

Both test line and control line appear.



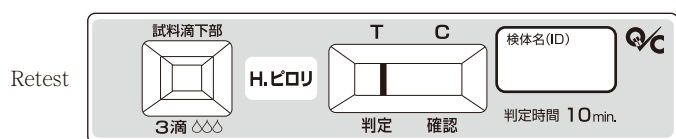
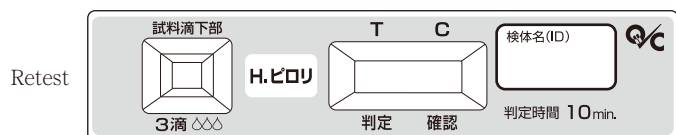
《Negative》

Only control line appears.



《Retest》

If both test line and control line do not appear or no control line appear, operational mistakes such as the insufficient sample volume are considered. Recheck test procedure and retest with new test plate. If the same result comes out in the retest again, confirm it with other method.



● Interpretational precautions

- In cases where test line and control line appear at 3~10 minutes after adding sample, it can be interpreted as positive. Negative should be interpreted at 10 minutes after adding sample. Streak line may appear temporarily due to flow of colloidal gold, but please note that this is not a test line. After interpretation time, colloidal gold can appear line-like due to drying of test plate with time. Therefore, interpret test results at the predetermined time.
- This product is used as an aid in the diagnosis for infection of *Helicobacter pylori*. In such cases where *Helicobacter pylori* antigen in specimen are below the detection limit of the test or specimen collection is not enough, test result could be interpreted as negative, even though patients are infected by *Helicobacter pylori*. Moreover, special factors in specimen could cause non-specific reaction and negative specimen could be interpreted as positive. The definitive diagnosis should be made comprehensively in conjunction with the assessment of clinical progress and another test result.

[Performance characteristics]

1) Performance

① Sensitivity

- When in-house positive control ^{note1)} was tested, a positive result was shown.

② Accuracy

- When in-house positive control was tested, a positive result was shown.
- When in-house negative control ^{note2)} was tested, a negative result was shown.

③ Reproducibility

- When in-house positive controls were tested three time simultaneously, positive results were shown in all cases.
- When in-house negative controls were tested three time simultaneously, negative results were shown in all cases.

Note 1) *Helicobacter pylori* antigen control solution is diluted by extraction reagent solution to be equivalent to 10ng/mL of calibration reference material

Note 2) Extraction reagent solution

④ Detection limit

2.5ng/mL

2) Correlation

Comparison with existing approval product (immunochromatographic assay)

Quick Chaser® H. pylori			
	Positive	Negative	Total
Other product (1)	61	3 ^{※2)}	64
Negative	4 ^{※1)}	72	76
Total	65	75	140

Sensitivity : 95.3%(61/64)

Specificity : 94.7%(72/76)

Accuracy : 95.0%(133/140)

※1 1 of 4 cases where results did not agree was also determined as positive by other product (2).

※2 3 cases where results did not agree were also determined as negative by other product (2).

Comparison with existing approval product (ELISA method)

Quick Chaser® H. pylori			
	Positive	Negative	Total
Other product (2)	59	0	59
Negative	6 ^{※3)}	75	81
Total	65	75	140

Sensitivity : 100.0%(59/59)

Specificity : 92.6%(75/81)

Accuracy : 95.7%(134/140)

※3 3 of 6 cases where results did not agree were also determined as negative by other product (1).

3) Calibration reference material (Standard material)

Helicobacter pylori (ATCC43504)

[Precautions for use and handling]

1) Precautions for handling (Prevention of danger)

- Infectious materials other than *Helicobacter pylori* could be included in sample (specimen). Handle sample (specimen) as potentially infectious materials.
- Upon use, wear protection devices (safety glasses, gloves, surgical masks etc.), and avoid direct contact with skin and eyes.
- If specimen and/or extraction reagent solution come in contact with eyes or mouth, flush with a plenty of water as a first aid treatment and seek medical attention if necessary.
- Material of membrane used for test plate is nitrocellulose. Do not use this product near the fire as nitrocellulose is extremely flammable.
- In case where the sample (specimen) is spattered, wipe off with ethanol for disinfectant.

2) Precautions for use

- ① Do not freeze this product. Store this product in accordance with description of instruction for use. Do not use frozen reagents as they could show false result by change of quality.
- ② Do not use this product beyond expiration date.
- ③ Use the test plate immediately after opening aluminum foil pouch. If test plate is left in a room for a long period of time, it may not react due to exposure to moisture.
- ④ Do not touch sample area, test line area and control line area directly by hands.
- ⑤ Avoid performing test in the place where the dry wind directly blows the surface of the test plate such as under air conditioner, to prevent uneven migration.
- ⑥ Do not use this product for purposes other than described in “intended use” of this instruction for use.
- ⑦ Test plate and extraction reagent solution (sold separately) is for single-use only.

3) Precautions for waste disposal

- ① Treat liquid waste and used utensils by any one of following methods because sample (specimen) could contain infectious material other than *Helicobacter pylori*.
 - a) Immerse in sodium hypochlorite solution (effective chlorine concentration of 1,000ppm) for 1 hour or more
 - b) Immerse in 2% glutaraldehyde solution for 1 hour or more
 - c) Autoclave at 121°C for 20 minutes or more
- ② Regarding disposal of used reagent and utensils, dispose of them in accordance with Local Regulation and Law of waste disposal.

[Storage • Expiry]

- Storage : 1~30°C
- Expiry : 24 months (as indicated on package)

Technical information
Telephone **+81-942-85-3845**

“Quick Chaser” is a registered trademark of Mizuho Medy Co., Ltd.

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