

PROFICIENCY (PHYSICIAN OFFICE LABORATORY) STUDY

One Step™+ *H. pylori* Rapid Test Device was evaluated at 3 different physicians' office laboratories using a panel of 90 coded samples. The proficiency panel contained negative, low positive and high positive specimens in either serum or whole blood. Tests were conducted by technical and non-technical personnel at three different institutions on three different days. The results obtained from 270 tests had a >99% agreement with the expected results. No significant differences were observed between the laboratories or personnel results.

INTERFERENCE STUDY










Possible interfering materials found in blood, including bilirubin, hemoglobin, triglycerides, or albumin, were tested in the **One Step™+ *H. pylori* Rapid Test Device** test at approximately 10-fold higher than normal physiological concentrations. These substance did not alter the test results of **One Step™+ *H. pylori* Rapid Test Device** test.

REFERENCES

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Symbols Key

 Lot Number	 Do Not Reuse
 Expiration Date	 For <i>in vitro</i> Diagnostic Use
 Store at 2-30°C	 Catalog Number
 Consult Instructions For Use	
 Contains sufficient for <n> tests	
 Medical device	

Distributed by:
HENRY SCHEIN INC.
135 DURYEA ROAD
MELVILLE, NY 11747 USA

P-52520
Rev 10/2021

HENRY SCHEIN® One Step™+ *H. pylori* Rapid Test Device

For *in vitro* Diagnostic Use
Rx Only

Immunoassay for the Qualitative Detection of Anti-Helicobacter pylori Antibody in Human Whole Blood, Serum or Plasma Specimens

CLIA Complexity:
CLIA Waived for Whole Blood
CLIA Moderate Complexity for Serum or Plasma

Catalog Number: 570-2778

INTENDED USE

One Step™+ *H. pylori* Rapid Test Device qualitatively detects anti-Helicobacter pylori antibody in human whole blood, serum, or plasma specimens. The test is intended for use as an aid in the diagnosis of *H. pylori* infection in adult patients with symptoms of gastrointestinal disorders.

SUMMARY AND PRINCIPLE

Helicobacter pylori, formerly known as Campylobacter pylori, are gram-negative microaerophilic spiral bacteria that have been identified and cultured since 1983¹. They can colonize the gastric mucosa for years², and their presence is strongly associated with chronic, diffuse, superficial gastritis of the fundus and antrum³⁻⁵. As a result, they are now believed to have an etiologic role in gastritis⁶⁻⁷. Recent evidence suggests that *H. pylori* gastritis may progress over several decades to chronic atrophic (type B) gastritis^{8,9}, a lesion that is a precursor of gastric carcinoma. The epidemiologic features of gastric carcinoma and *H. pylori* infection are similar¹⁰ and recent studies suggest that *H. pylori* infection may be a risk factor for gastric carcinoma^{11,12}. Until recently diagnosis of infection with *H. pylori* required endoscopy and identification of the organism by means of subsequent culture of the bacteria and/or recognition of spiral organisms in histologically evaluated sections of gastric tissue. However, the expense and invasive nature of this procedure make endoscopy impractical for epidemiologic studies. Serology has become the method of choice for such studies. There is excellent correlation between a classical clinical presentation of gastritis, the presence of *H. pylori* in the stomach and elevated serum levels of anti-*H. pylori* antibodies¹³⁻¹⁵. Positive results can justify a short empirical trial of antimicrobial therapy in gastritis of unknown origin, and response to treatment can be serially monitored because levels of *H. pylori*-specific antibodies can be expected to fall significantly after successful antibacterial therapy¹⁶.

The **One Step™+ *H. pylori* Rapid Test Device** Anti-*H. pylori* Antibody test utilizes indirect solid-phase immunoassay technology for the qualitative detection of *H. pylori* antibodies. **One Step™+ *H. pylori* Rapid Test Device** consists of *H. pylori* antigen on the test membrane and *H. pylori* antigen plus anti-human immunoglobulin antibodies coated on gold particles in the dye pad. Thus, in principle, the results of **One Step™+ *H. pylori* Rapid Test Device** may differ from the results of assay using only anti-IgG as a detector. In the test procedure, patient specimen is added in the upper area of the Sample well (S) located below the Result window.

The Developer solution is then added in the Sample well. The solution mobilizes the dye conjugated to *H. pylori* antigen and to anti-human immunoglobulin antibodies. If any anti-*H. pylori* antibody is present in the

sample, the dye conjugate will bind to the *H. pylori* antigen band impregnated on the test membrane. Visualization of the antigen band at the Test position (T) will occur only when the anti-*H. pylori* antibody is present in the sample. As the antibody-dye conjugate continues to move along the test membrane, it will be captured by a species specific antibody located at the Control position (C) to generate a colored band regardless of the presence of *H. pylori* antibodies in the sample. The presence of two colored bands, one at the Test position and the other at the Control position, indicates a positive result, while the absence of a colored band at the Test position indicates a negative result.

REAGENTS AND MATERIALS PROVIDED

Materials Provided

- **One Step™+ *H. pylori* Rapid Test Device**: 20 test devices containing a membrane strip coated with *H. pylori* antigen and a pad with indicator conjugates in a protein matrix.
- 1 Positive Control
- 1 Negative Control
- 20 capillary tubes
- Developer solution containing 0.1% sodium azide
- Package insert

Materials required but not provided:

- Vacutainer tubes for either serum or plasma procedure
- Anticoagulant (i.e., CPDA-1, heparin, or EDTA) for plasma
- Centrifuge
- Lancet

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- For prescription use only.
- Do not interchange materials from different product lots and do not use beyond the expiration date.
- Use separate clean capillary tubes for different specimens. Do not pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
- All patient samples should be handled as if they were capable of transmitting disease. Observe established precautions against microbiological hazard throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Developer solution in this kit contains 0.1% sodium azide as a preservative, which may react with lead or copper in plumbing to form potentially explosive metal azides. Upon disposal, always flush with a large volume of water to prevent azide buildup in drains.
- The **One Step™+ *H. pylori* Rapid Test Device** device should remain in its original sealed pouch until ready for use. Do not use the test if the pouch is damaged.

STORAGE AND STABILITY

One Step™+ *H. pylori* Rapid Test Device test kit should be stored at 2–30°C (35–86°F) in the original sealed pouch. The storage conditions and stability dating given were established under these conditions. The kit is stable until the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Anticoagulated Whole Blood:

- Whole blood collected over sodium heparin, lithium heparin, citrate or EDTA can be used. Mix whole blood by inversion and use in the test as outlined in the Test Procedure. Whole blood can be stored at 2–8°C for 24 hours.

Fingerstick Whole Blood:

- Prick the finger and collect the blood in capillary tube to the 25 µL mark. Follow the Test Procedure.

Serum:

- Collect blood sample into a tube containing no anticoagulant. Allow the blood to clot at room temperature (18–30°C) and then centrifuge at 1500 x g for ten minutes at room temperature.

Plasma:

- Collect whole blood sample into a tube containing anticoagulant such as CPDA-1, heparin, or EDTA.
- Remove the serum or plasma from the blood cells as soon as possible to avoid hemolysis. When possible, clear, non-hemolyzed specimens should be used. Mildly hemolyzed samples do not affect the test result, but will create an undesirable reddish background in the Result window.
- Specimens containing any particulate matter may give inconsistent test results. Such specimens should be clarified by centrifugation prior to testing.

Storage of specimens:

- Refrigerate all specimens at 2–8°C until ready for testing. If serum or plasma specimens will not be tested within 48 hours, they should be frozen and stored at -20°C or below. Specimens should not be repeatedly frozen and thawed.
- Bring samples to room temperature (18–30°C) before testing. Frozen samples must be completely thawed, thoroughly mixed, and brought to room temperature prior to testing.
- If specimens are to be shipped, they should be packed in compliance with Federal and carrier regulations covering transportation of etiologic agents.

PROCEDURAL SUMMARY

Allow specimens and the **One Step™+ H. pylori Rapid Test Device** test kit to warm to room temperature (18–30°C) before testing • Do not open the sealed pouch until you are ready to perform the test.

- Several tests may be run at one time.
- Do not reuse a lancet.
- To avoid cross-contamination, use a new capillary tube for each specimen.
- To avoid contamination, do not touch the tip of the Developer solution dropper bottle to skin or to the test device.
- Label the device with the patient's name or control number.
- When adding the Developer solution, hold the dropper bottle in a vertical position above the lower area of the Sample well (S).
- After testing, dispose of the test device and the capillary tube following good laboratory practices. Consider each material that comes in contact with the specimen to be potentially infectious.

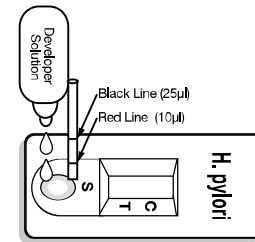
TEST PROCEDURE

Test Procedure Directions

Step 1. Remove a device from pouch and place on flat surface.

Step 2. For serum or plasma fill a capillary tube to the red line (10 µl). For whole blood fill a capillary tube to the black line (25 µl). Apply sample by lightly tapping the capillary on the pad of the UPPER AREA of the Sample well (S).

Step 3. Add 2 to 3 drops of Developer Solution onto the LOWER AREA of the Sample Well (S).



Step 4. Read result at 10 minutes. (Do not read after 15 minutes).

INTERPRETATION OF RESULTS

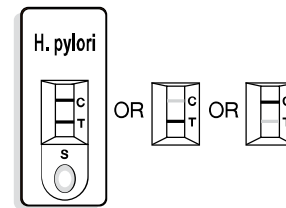
Positive:

One colored band each at the Test position (T) and at the Control position (C) indicates that antibodies against H. pylori have been detected.

Note: The test result can be read as soon as a distinct pink-purple colored Test line (T) and a colored Control line (C) appear. Any shade of pink-purple colored Test line should be reported as a positive result.

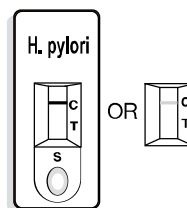
Possible positive results :

- Two strong colored lines at both the Test (T) and Control (C) position.
- One strong Test line (T) and one light colored Control line(C).
- One light colored Test line (T) and one strong colored Control line (C).



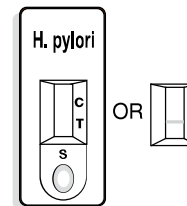
Negative:

Only one colored Control line (C), with no colored Test line (T) indicates that antibodies against H. pylori have not been detected.



Invalid:

A distinctive colored Control line (C) should always appear. The test is invalid if no Control line forms. Repeat the test with a new **One Step™+ H. pylori Rapid Test Device** test.



LIMITATIONS OF THE PROCEDURE

- The results obtained by this kit should be used only to evaluate patients with other clinical symptoms of gastrointestinal disease. This assay is not intended for use with asymptomatic patients.
- The performance characteristics of this test with specimens from pediatric patients have not been established.
- A positive result only means the presence of antibodies to H. pylori and does not indicate any disease status of the patient. A positive test result does not allow one to distinguish between active infection and colonization by H. pylori. A negative result suggests that antibodies to H. pylori are not present, or are present at a level below the detection limit. If the test result is negative and infection of H. pylori is suspected, additional testing such as culture and histological analysis is recommended.

QUALITY CONTROL

Good laboratory practice recommends the periodic use of external control materials to ensure proper kit performance. The included positive and negative controls can be run in place of serum or plasma. When testing the external controls, add 1 drop of control solution on the upper area of the Sample well(S) and 2 drops of Developer solution on the lower area of the Sample well(S), then read result at 10 minutes.

When the test has been performed correctly and the device is working properly, a distinct colored line will always appear at the Control position (C). The colored line at the Control position (C) is considered an internal positive procedural control. If the line does not appear, a new device should be tested. If the problem persists, contact Henry Schein Technical Services at 1-800-772-4346.

When the test has been performed correctly and the device is working properly, the background in the Result window will clear, providing a distinct test result. This clearing background in the Result Window is considered an internal negative procedural control.

EXPECTED VALUES

- H. pylori is detectable in nearly 100% of adult patients with duodenal ulcer and about 80% of patients with gastric ulcer.^{13,17} **One Step™+ H. pylori Rapid Test Device** demonstrated positive results for 94% of patients with a symptom of ulcer and positive results on 80% of gastritis patients.
- The prevalence of H. pylori antibody increases with age, and is detectable in 5% of children, about 33% in blood donors, and approaches 50% at age 60 in the normal population of industrialized nations.^{16,18} More than 25% of these infected patients are asymptomatic. Other factors such as socioeconomic status, ethnic group, different populations, geographical location and the type of clinical symptoms associated with the infection also contribute to the observed variations in prevalence.
- Asymptomatic and untreated patients continue to test IgG seropositive as long as the H. pylori organisms are present, even after histological resolution¹⁶. Hence, positive results are simply consistent with the diagnosis of H. pylori-associated gastritis or duodenal ulcer; whereas, negative results are strong evidence against these diagnoses.

PERFORMANCE CHARACTERISTICS

Clinical specimens were collected from 207 symptomatic and asymptomatic individuals who presented for endoscopic examination. The age range was 19-83 years with a mean age of 52 years. The performance characteristics of **One Step™+ H. pylori Rapid Test Device** were evaluated by comparison to biopsy/histology, agglutination test and ELISA for detection of anti-H. pylori antibody. The results are summarized in tables 1–3.

Table 1

One Step™+ H. pylori Rapid Test Device Test vs. Biopsy / Histology

		Biopsy/Histology		
		Positive	Negative	Total
One Step™	Positive	71	14	85
H. pylori	Negative	3	115	118
Whole blood	Total	74	129	203

When biopsy/histology was used as a reference, the **One Step™+ H. pylori Rapid Test Device** test demonstrated 95.9% sensitivity, 89.1% specificity and 91.6% agreement. Four tests were excluded in the calculation due to indeterminate results.

Table 2

One Step™+ H. pylori Rapid Test Device Test vs. Agglutination Test

		Agglutination		
		Positive	Negative	Total
One Step™	Positive	80	8	88
H. pylori	Negative	6	113	119
Whole blood	Total	86	121	207

When the agglutination test was used as a reference, the **One Step™+ H. pylori Rapid Test Device** Test demonstrated 93.2% agreement.

Table 3

One Step™+ H. pylori Rapid Test Device Test vs. ELISA

		ELISA		
		Positive	Negative	Total
One Step™	Positive	78	10	88
H. pylori	Negative	6	113	119
Whole blood	Total	84	123	207

When the ELISA was used as a reference, the **One Step™+ H. pylori Rapid Test Device** test demonstrated 92.3% agreement.

MATRICES EFFECT STUDY

Effect of specimen matrices on the result of the **One Step™+ H. pylori Rapid Test Device** Test was evaluated using 59 matched specimen

sets each consisting of venous whole blood, capillary whole blood, plasma and serum. Of the 59 samples tested, 46 samples were positive and 13 samples were negative. Excellent agreement (>99%) was found between venous whole blood, capillary whole blood, plasma and serum indicating no significant effect of matrices on the test.

REPRODUCIBILITY

Reproducibility of **One Step™+ H. pylori Rapid Test Device** was evaluated by testing negative, low positive and high positive samples. The samples were tested in replicates of 10 in a blind study by 4 technicians, on 3 different dates and at 4 different locations. The results showed 100% agreement with the expected results.