Rely™ *H. pylori* Rapid Test

INTENDED USE

For the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum or plasma to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older.

CLIA CATEGORY

Whole Blood	Waived
Serum/Plasma	Moderately Complex

METHOD: Immunoassay

SPECIMEN: Whole Blood (from Fingerstick or Venipuncture), Serum or Plasma

ASSAY TEMPERATURE:

Room Temperature (15 – 30 °C)

CONTROLS: A Positive and a Negative Control (Follow directions for Internal Control and External Control below.)

LIMITATIONS: 1. The RELY™ *H. pylori* Rapid Test should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease and is not intended for use with asymptomatic patients.

2. The RELY™ *H. pylori* Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* IgG antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.

3. The RELY™ *H. pylori* Rapid Test will only indicate the presence of *H. pylori* IgG antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *H. pylori* infection.

4. Grossly hemolyzed specimens will yield invalid results. Strictly follow these Instructions For Use to obtain accurate results.

5. A positive result does not allow one to distinguish between active infection and colonization by *H. pylori*.

6. A positive result only indicates the presence of IgG antibody to *H. pylori* and does not necessarily indicate that gastrointestinal disease is present.

7. A negative result indicates that IgG antibody to *H. pylori* is not present or is below the detection limit of the test.

8. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

9. Literature references have suggested cross reactivity of IgG antibody with a closely related organism, Borrelia burgdorferi. Performance of this assay has not been evaluated with this organism. Therefore, the specificity of this test cassette
is not known if this organism is encountered.

10. Literature references have suggested that high triglyceride levels interfere with IgG antibody. However, performance of

this assay has not been evaluated with this substance. Therefore, test results of these cassettes are not known if high levels of this substance are encountered.

11. This assay has not been established for patients under 18 years of age.

PRINCIPLE: *H. pylori* is a small, spiral-shaped bacterium that lives on the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and

chronic gastritis. Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease.

Sample dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining. Noninvasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods. Individuals infected with *H. pylori* develop serum IgG antibodies which correlate strongly with histologically confirmed *H. pylori* infection.6,7,8 The RELY™ *H. pylori* Rapid Test is a simple test that utilizes a combination of *H. pylori* antigen coated particles and antihuman IgG to qualitatively and selectively detect *H. pylori* IgG antibodies in whole blood, serum or plasma.

The One Step *H. pylori* Test Device (Whole Blood/Serum/ Plasma) is a qualitative membrane based immunoassay for the detection of *H. pylori* antibodies in whole blood, serum or plasma. In this test procedure, anti-human IgG is immobilized in the
specimen zone of the cassette. The specimen reacts with *H. pylori* antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-human IgG. If the specimen contains *H. pylori* IgG antibodies, a colored line will appear in the specimen zone indicating a positive result. If the specimen does not contain *H. pylori* IgG antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control zone, indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE: RELY™ *H. pylori* test cassettes, controls and buffer are stable until the expiration dates printed on their respective labels when

stored at 2-30°C. The test cassettes must remain in their sealed pouches until use. **Do Not Freeze! Do not use after expiration date.**

SPECIMEN COLLECTION:

The RELY™ *H. pylori* Rapid Test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

1. To collect venipuncture whole blood specimens: Collect anti-coagulated blood specimen (sodium or lithium heparin,

potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.

2. To collect fingerstick whole blood specimens:
a. Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
b. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
c. Puncture the skin with a sterile lancet. Wipe away the first drop of blood.
d. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
e. Touch the end of the capillary tube to the blood until filled to the line; avoid air bubbles.
f. Place the bulb onto the top end of the capillary tube.
g. Squeeze the bulb to dispense the whole blood.

3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at ambient room temperature for prolonged periods.

Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Whole blood

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collected by fingerstick should be tested immediately. Do not freeze whole blood specimens. Serum or plasma specimens may
be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Frozen specimens must be completely thawed and mixed well prior to testing.

Specimens should not be frozen and thawed repeatedly. Bring samples to room temperature prior to testing. If specimens are to be shipped, they should be packed in compliance with federal
regulations covering the transportation of etiologic agents.

PROCEDURE: 1. Allow the test cassette, specimen, buffer and controls to reach ambient room temperature (15 – 30 °C) before testing.

2. Remove the test cassette from the foil pouch. For best results, perform the test immediately after opening the foil pouch.

3. Place the test cassette on a clean and level surface.
For Whole Blood (Venipuncture) specimens: Hold the dropper upright and add 2 drops of whole blood (approx. 50 µL) to the sample well of the test cassette. Then add 1 drop of buffer to the sample well. Start the timer.

For Whole Blood (Fingerstick) specimens: Add one capillary tube of blood (approx. 50 µL) to the sample well of the test cassette. Then add 1 drop of buffer to the sample well. Start the timer.

For Serum or Plasma specimens: Hold the dropper upright and add 2 drops of serum or plasma (approx. 50 µL) to the sample well of the test cassette. Then add 1 drop of buffer to the sample well. Start the timer. Avoid trapping air bubbles in the sample well.

4. Wait for the red line(s) to appear. The result should be read at 10 minutes. The background should be clear before the result is read.

NOTE: Low levels of *H. pylori* IgG specific antibodies might

RESULTS:

Positive*: Two distinct red lines appear. One line should be in the control zone (C) and another line should be in the specimen zone (S). A positive result means that *H. pylori* IgG specific antibodies were detected in the specimen.

***NOTE:** The shade of the red color in the specimen zone (S) will vary based on the amount of *H. pylori* IgG specific antibodies in the specimen. Any shade of red in the specimen zone (S) should be considered positive.

Negative: One red line appears in the control zone (C). No apparent red or pink line appears in the specimen zone (S). A negative result means that *H. pylori* IgG specificantibodies were not found in the specimen or are below the detection limit of the test.

Invalid: No line appears in the control zone (C). If this occurs, read the directions again and repeat the test with a new test cassette. If the result is still invalid, stop using the test kit and contact Stanbio Laboratory's Technical Service Department at
1-800-531-5535.

QUALITY CONTROL:

Internal Quality Control: Internal procedural controls are included in the test. A red line appearing in the control zone (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear
background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External Quality Control: It is recommended that a positive and negative external control be run every 20 tests, and as deemed necessary by your internal laboratory procedures.

External positive and negative controls are supplied in the kit. If controls do not perform as expected, assay results are invalid.

Procedure for External Quality Control Testing: Using the positive or negative external controls in place of a patient specimen, add 2 drops of positive or negative control solution to the sample well of a new test cassette, then add 1 drop of buffer. Start the timer. Continue with Step 4 in the Test Procedure section.

REFERENCE: Stanbio Rely™ *H. pylori* Rapid Test, Procedure #6300

Date of Review/Revision

Reviewed by_____
Lab Director/Supervisor