**RELY® H. pylori Rapid Test Procedure No. 6300**

**Intended Use**

For the Qualitative Detection of IgG Antibodies to Helicobacter pylori (H. pylori) in Whole blood, Serum or Plasma.

**CLIA Category**

Whole Blood Waived
Serum/Plasma Moderately Complex

**Summary and Principle**

The RELY® H. pylori Rapid Test is a rapid chromatographic immunoassay 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. 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. Non-invasive 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.1,2 The RELY® H. pylori Rapid Test is a simple test that utilizes a combination of H. pylori IgG antibody coated particles and anti-human IgG to qualitatively and selectively detect H. pylori IgG 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 IgG antibody 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 control line will always appear at the control zone, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**Reagents**

RELY® H. pylori Rapid Test Cassette, Ref. No. 6301
Sealed foil pouch containing one (1) test cassette comprised of a combination of Helicobacter pylori antigen coated particles and anti-human IgG coated membrane.

RELY® H. pylori Positive Control, Ref. No. 6303
Diluted human plasma containing H. pylori-specific IgG, 0.09% sodium azide

RELY® H. pylori Negative Control, Ref. No. 6304
Diluted human plasma, 0.09% sodium azide

RELY® H. pylori Buffer, Ref. No. 6302
Contains 0.02% sodium azide

**Precautions:**

For “In Vitro Diagnostic Use.” Do not use after expiration date. Normal precautions exercised in handling laboratory reagents should be followed. Do not pipette by mouth. Controls and buffer contain sodium azide, which may be toxic if ingested. Sodium azide may also react with lead and copper cleaning to form highly explosive metal azides. Refer to Material Safety Data Sheet for any updated risk, hazard or safety information. Dispose of used or expired reagents according to your laboratory and governmental requirements. Do not eat, drink or smoke in the area where the specimen and kits are handled. The positive and negative controls contain human plasma. Handle controls and all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed. Humidity and temperature can adversely affect results.

**Reagent Preparation:**

The RELY® H. pylori test cassettes, controls and buffer are supplied ready-to-use.

**Reagent Storage and Stability:**

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!

**Specimen Collection, Storage and Preparation**

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

1. **Venipuncture whole blood specimens:** Collect 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-hemolysed specimens.
4. 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 24 hours of collection. Whole blood collected by fingerstick should be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Bring samples to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
   a. If samples are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

**Material Provided**

**Test cassettes (20)**
Disposable pipettes (20)
Disposable heparinized capillary tubes (20) and dispensing bulb (1)
Positive control (0.5 mL)
Negative control (0.5 mL)
Buffer (10 mL)
Procedure card (1)
Instructions for use (1)

**Material Required But Not Provided**

**Specimen collection container (for venipuncture whole blood)**
Lancet (for fingerstick whole blood only)
Centrifuge (for serum and plasma only)

**Timer**

**Test 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.
4. 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.
5. 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.
6. 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.

**NOTE:** Low levels of H. pylori IgG antibodies might result in a weak line in the specimen zone (S) after a long period of time. Do not read the result after 15 minutes.

**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.

**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.

**Negative**: A negative result means that proper volume of specimen has been added and membrane wicking has occurred. Include the positive control to ensure that proper control is operating. If the positive control is negative, check expiration date and availability of positive control. If the positive control is positive, check expiration date and availability of negative control. If both controls are negative, check the expiration date and availability of both controls. If both controls are positive, the negative control is not performing properly.

**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 kit and contact Stanbio Laboratory’s Technical Service Department at the numbers listed at the end of this procedure.

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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.

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.

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.

Fingerstick                          Culture/Histology

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<td>+</td>
<td>54/69 (78%)</td>
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- Sensitivity: 54/69 = 78% (75% - 84%)*
- Specificity: 54/2 = 94% (90% - 98%)*
- Accuracy: 108/81 = 85% (80% - 90%)*

*Denotes 95% Confidence Interval

The correlation between the RELY® H. pylori Rapid Test and the comparator rapid diagnostic test kits is summarized below.

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**Venous Whole Blood**

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**Fingertip**

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**References**


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Stanbio Laboratory • 1261 North Main Street • Boerne, Texas 78006 USA
For Technical Service call: 1-800-531-5355 • (830) 249-0772
Fax: (830) 249-0851 • email: orders@stanbio.com
http://www.stanbio.com

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