

# CLIAwaived<sup>™</sup> Inc.

## H. Pylori Whole Blood Rapid Test

A CLIA Waived Qualitative *In-Vitro* Diagnostic Test for External Use only



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### INTENDED USE

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The **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** is a rapid qualitative immunoassay intended to detect the presence of IgG antibodies specific to *Helicobacter pylori* (*H. pylori*) in human whole blood. The test provides an aid in the diagnosis of *H. pylori* infection and is for use by health care professionals only.

This device provides a presumptive result and should be used in conjunction with patient's symptoms and physician's other diagnostic results.

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### SUMMARY AND EXPLANATION

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*Helicobacter pylori* has been associated with a variety of gastrointestinal diseases.<sup>1-3</sup> *H. pylori* infections occur in human populations throughout the world. In developed countries, about 50% of the population may have *H. pylori* infection by the age of 60 years, while only 10-20% of adults in the third decade of life have it.<sup>4,5</sup>

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### PRINCIPLE OF THE TEST

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This assay is a chromatographic lateral flow immunoassay. If the IgG antibodies specific to *H. pylori* are present in the specimen, the Test (T) Line will develop as a burgundy-colored band. If antibodies to *H. pylori* are not present or are present below the detectable level, no T line will develop. The Control (C) Line serves as an internal qualitative control of the test system. It should always appear as a burgundy-colored band regardless of the presence of antibodies to *H. pylori*. If the control line does not develop in 4 minutes, the test is considered invalid.

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### REAGENTS AND MATERIALS SUPPLIED

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- 25 Test devices/kit, each device is sealed in a pouch with a disposable dropper.
- 1 Bottle of Wash Buffer containing 7 ml PBS solution with 0.02% sodium azide as a preservative.
- 1 Package Insert (Instruction for Use)
- 1 Kit Contents Sheet

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### MATERIALS NEEDED BUT NOT PROVIDED

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- Lancet or other blood collection device
- Alcohol Swab
- Timer

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### PRECAUTIONS

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- The instructions must be followed to obtain accurate results.
- This test is for professional qualitative *in-vitro* diagnostic use only.
- Do not use the device if the foil pouch is broken or it is opened for over 30 minutes.
- Do not use expired devices.
- Dispose of all specimens and used assay materials as potentially biohazardous.
- Do not reuse the device.

# CLIAwaived<sup>TM</sup> Inc.

## H. Pylori Whole Blood Rapid Test

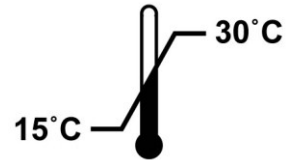
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### STORAGE

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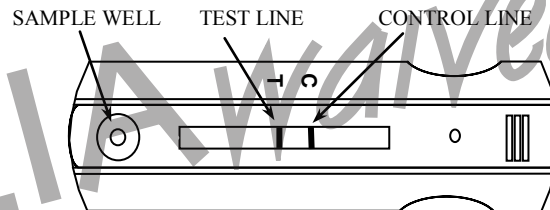
- Store kit at room temperature 59°-86°F (15°-30°C).
- Do not freeze kit.
- When properly stored, contents are stable until the expiration date printed on the outer box and the sealed foil pouch.



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### STRUCTURE OF THE TEST

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*NOTE: Diagram represents a positive test.  
Both the Control (C) Line and Test (T) Line are present.*

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### QUALITY CONTROL

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#### **Built-in Control Features:**

The **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** contains built-in control feature, the C-line. The appearance of the burgundy C-line indicates that an adequate volume of specimen and wash buffer has been applied and that an adequate flow occurred. If the control line does not develop in 4 minutes, the test is considered invalid. If the result is invalid, repeat the test with a new sample and test device.

#### **External Quality Control:**

External controls (positive and negative) are recommended to monitor the performance of the assay.

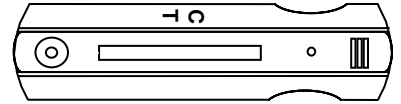
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**Whole Blood Sample Collection & Operating Instructions**

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

**Step 1.**



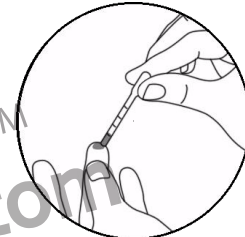
**Step 2** Clean patient's finger with an alcohol swab. Puncture the fingertip with the lancet. Wipe away first sign of blood. Gently rub the hand from palm to finger to help form a drop of blood at the puncture site.

**Step 2.**



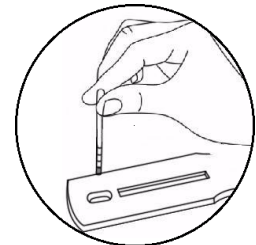
**Step 3** Use the provided dropper to pick up the blood. Fill the blood to the first line of the tip end.

**Step 3.**



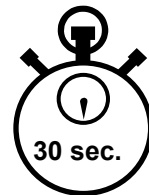
**Step 4** Dispense the entire contents of the dropper into the sample well.

**Step 4.**



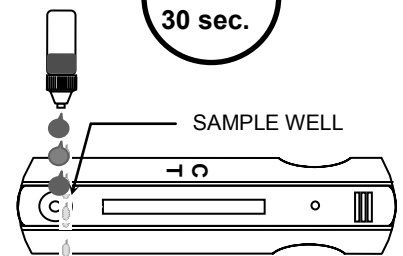
**Step 5** Allow 30 seconds for the sample to be absorbed.

**Step 5.**



**Step 6** Add (3) drops of wash buffer into the sample well.

**Step 6.**



**Step 7** The results should be read within 4-7 minutes.

**Step 7.**



**DO NOT INTERPRET THE RESULTS AFTER 7 MINUTES.**

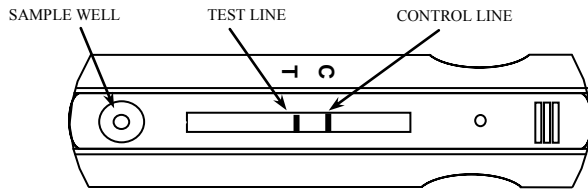
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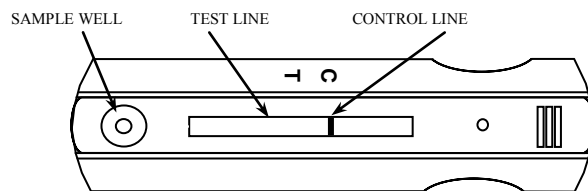
**HOW TO READ THE TEST RESULTS**

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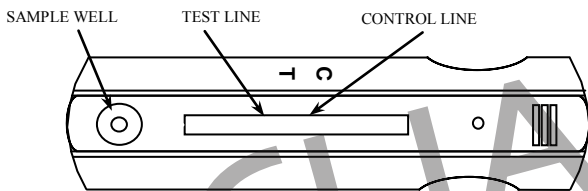


**Positive** (Both C Line and T Line are Visible)

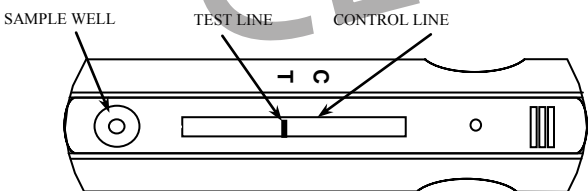
Positive results should be evaluated with confirmatory methods available to the physician



**Negative** (Only C Line is Visible)



**Invalid** (No C Line & No T Line)



**Invalid** (No C Line, T Line Present)

If the result is invalid, repeat the test with a new sample and test device

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**FREQUENTLY ASKED QUESTIONS**

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**What does it mean if the T line is very faint?**

Even a faint T line, which appears in the test region between 4 and 7 minutes, indicates a positive result.

**Is it necessary to confirm a positive test result?**

Yes. This device provides a preliminary result and should be used in conjunction with the patient's symptoms and the physician's other diagnostic information to make a confirmed diagnosis.

**How do I know if the test worked properly**

The **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** has a built-in control feature. The appearance of the burgundy C line indicates that a sufficient amount of solution has been applied in the sample well and that an adequate flow of specimen and buffer occurred. The C line should always be present. If the C line does not appear within 4 minutes, the test result is invalid. If the result is invalid, retest using a new test device.

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### Limitations

The **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** is a qualitative assay for *in-vitro* diagnostic use only. A positive result does not distinguish an active from an inactive infection: but only the presence of antibodies to H. pylori. Positive results should always be evaluated in conjunction with other confirmatory methods available to the physician. If the test is negative and an infection is suspected additional follow-up testing is recommended.

### Expected Waiver Performance

Sixty (60) lay users from three different sites evaluated the device. Each participant tested an H. pylori negative, a weak positive, and a positive sample. The results from the lay users agreed 100% with the results from professionals and 100% with the confirmatory results.

### Performance Characteristics

#### Sensitivity and Specificity

The **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** was evaluated with 296 confirmed clinical serum specimens, 144 were positive and 152 were negative. All the specimens were blind labeled. The evaluations were conducted in house. The sensitivity of this device is 95.1% (137/144) and the specificity is 94.1% (143/152).

		CONFIRMED CLINICAL RESULTS	
		POSITIVE	NEGATIVE
<b>CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test</b>	POSITIVE	137	9
	NEGATIVE	7	143

#### Comparison with a Predicate Device

A side-by-side comparison study between this **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** and a predicate device was conducted. Two hundred and ninety-six (296) clinical serum specimens were evaluated with both devices. The results are summarized in the table below. The agreement between these two devices is 97.9% (142/145) for positive specimens and 97.4% (147/151) for negative specimens. This study demonstrated that this **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** is substantially equivalent to the predicate device.

		PREDICATE H. PYLORI TEST	
		POSITIVE	NEGATIVE
<b>CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test</b>	POSITIVE	142	4
	NEGATIVE	3	147

#### Cross Reactivity

H. pylori positive and negative specimens were spiked with *C. jejuni*, *C. fetus*, *C. coli*, *E. coli*, *Proteus*, *N. gonorrhoea*, *Streptococcus* and *Staphylococcus*. No cross-reactivity was noted; therefore, indicating that the **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** has a high degree of specificity for human antibodies to *H. pylori*.

#### Interference

The results of the **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** were not affected by elevated levels of serum albumin, bilirubin, hemoglobin, glucose, uric acid and lipids.

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### Reproducibility

An evaluation of the **CLIAwaived, Inc. H. Pylori Whole Blood Rapid Test** was conducted at three Physicians' Offices using a panel of coded specimens. Physician office personnel with diverse educational backgrounds and work experience at three different locations performed testing. The proficiency panel contained negative (20), moderate positive (20) and high positive (20) specimens. Each specimen level was tested a minimum of three replicates at each site over a period of three days. The results obtained agreed 100% for two sites and 98.3% for one site with the expected results. No significant differences were observed within run (3 replicates), between runs (3 different assay days) or between sites (3 different locations).

### References

1. *Marchall, BJ, McGeachie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. 149: 439-44; 1985.*
2. *Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New Engl. J. Med. 322:909-916;1990.*
3. *Parsonnet, J, Freidman, GD Vundersteen, DP, Chang, Y, Vogelman, JH, Orentreigh, N and Sibley, RK. Helicobacter pylori infection and the risk of gastric carcinoma. New Engl. J. Med. 325: 1127-31; 1991.*
4. *Marshall, BJ, Warren, JR and Blincow, ED. Prospective double blind trial of duodenal ulcer relapse after Geradication of Campylobacter pylori. Lancet. December 1437-42; 1988.*
5. *Graham, DY et al. Effect of treatment of Helicobacter pylori infection on the long-term recurrence of gastric or duodenal ulcer. Annals of Internal Med. 116: 705; 1992.*

### Legend

 Do not reuse	 Use by YYY-MM-DD or YYYY-MM
 Batch Code	 Serial number
 Caution, consult accompanying documents	 Catalog number
 Manufacturer	 Temperature limitation
 Contains sufficient for <n> tests	 Keep away from sunlight
 <i>In vitro</i> diagnostic medical device	 Keep away from moisture
 Consult instructions for use	 CE Mark
 Recycle	 Authorized representative in the European Community

### EC REP

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### H. Pylori Whole Blood/Serum Cassette Test

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