

MiraWell®

Rapid *Helicobacter pylori* Test

For Use with Serum, Plasma and Whole Blood

Package Insert

INTENDED USE

The MiraWell® Rapid *H. pylori* Test (MiraWell *H. pylori*) is a single use, qualitative immunoassay for the detection of antibodies to *Helicobacter pylori* in human whole blood, serum or plasma specimens. This product is intended for use in clinical and point-of-care settings to aid in the diagnosis of infection with *H. pylori*.

INTRODUCTION

H. pylori is a very common infection of the stomach and one of the most common infections in the world. Infection with *H. pylori* is related to the development of stomach and duodenal ulcers, and it is likely that it may be related to cancers involving the stomach. Anyone exposed to *H. pylori* will produce antibodies, which are indicators of infection. The detection of such antibodies represents a reactive test result (indicating that the individual is *H. pylori*-infected), but is not necessarily a diagnosis. The absence of antibodies at the time of testing (indicating that the individual is not *H. pylori*-infected) is indicated by a non-reactive test result but does not totally rule out the possibility of infection as it may take up to three months to develop antibodies after exposure.

The MiraWell Rapid *H. pylori* Test is a rapid, flow-through device developed and manufactured by MedMira Laboratories (CANADA). This test qualitatively detects the presence of antibodies to *H. pylori* in serum, plasma or whole blood specimens. The simple testing procedure of the MiraWell Rapid *H. pylori* Test involves placing a drop of the serum, plasma or whole blood sample through the pre-filter onto the coated test membrane and allowing it to flow through the membrane. If the sample contains *H. pylori* antibodies, they are captured on the test membrane. The test result is visualized at a colored end point through a reaction with a proprietary detection agent and can be interpreted immediately.

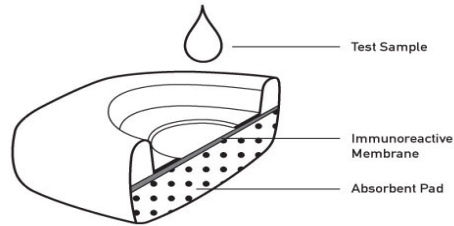


Figure 1: MedMira's Rapid Flow-Through Technology Platform

Deploying its distinctive flow-through testing platform; MedMira's tests utilize a single buffer solution for preparation and performance of the test and unique colorimetric agent, which allows for a visual interpretation of test results. The testing procedure is completed within 3 minutes. Precision pipetting, refrigeration or specialized equipment, including timer, **are not** required to perform the MiraWell Rapid *H. pylori* Test.

CONTENTS

Each Mylar pouch contains:

- 1 test cartridge with attached blue Specimen Filtration Unit
- 1-1mL Universal Buffer Solution (white-capped)
- 1 InstantGold™ Cap (green colored)
- 1 Diluent Buffer vial (red-capped)
- 1 disposable pipette
- 1 lancet
- 1 alcohol swab

WARNINGS

1. Read this instruction sheet completely and carefully prior to use of MiraWell *H. pylori*. If the directions are not followed exactly, inaccurate test results may occur.
2. Perform MiraWell *H. pylori* on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.

Safety Recommendations:

1. Handle specimens, and all materials contacting specimens as if capable of transmitting infectious agents.
2. Do not smoke, eat, or drink in areas where specimens or test reagents are handled. Do not pipette by mouth.
3. Wear disposable gloves when testing patient specimens.
4. Dispose of all test specimens and materials used in the MiraWell *H. pylori* as directed by governing infectious waste guidelines.
5. Sodium azide is used as a preservative in the Universal Buffer. To prevent formation of lead or copper azide, flush drains thoroughly with water after disposing of solutions containing sodium azide.

Handling Precautions

1. Use each test cartridge, Specimen Filtration Device, InstantGold™ Cap, Diluent buffer, and disposable pipette only once and dispose of properly. **Do not reuse these components.**
2. **Do not touch or mark on the immunoreactive test membrane.**
3. Exercise care in handling test components to prevent contamination.

INSTRUCTIONS

Please read the following items carefully before performing the test.

- Do not use after the expiration date printed on the outside box or on the Mylar pouch
- Store in a dry place at 2-30°C
- Keep out of reach of children
- For *in vitro* diagnostic use only. Not to be taken internally
- Do not open the Mylar pouch until you are ready to start the test
- Dispose with care of all test materials after use

DIRECTIONS FOR USE

Specimen Preparation

1. The MiraWell *H. pylori* can be used to test serum, plasma or whole blood specimens. Plasma obtained using EDTA, heparin, or sodium citrate as anticoagulants is suitable for testing.
2. Specimens may be tested immediately upon receipt or stored at 2 - 8°C for up to five (5) days prior to testing. Serum or plasma specimens should be stored at -20°C or below if storage is necessary for more than five (5) days.
3. Particulate matter can block the test membrane or cause high background colour making interpretation of results difficult. **Cloudy or viscous specimens should not be used for testing.**

Specimen Handling

1. For serum or plasma that has been previously frozen:
 - a. Thaw completely at room temperature (15-27°C) and mix thoroughly by gently tapping the bottom of the capped tube.
 - b. Centrifuge an aliquot of the specimen in a small, capped tube at room temperature (15-27°C) at 6000 rpm for at least five (5) minutes and use only the clear supernatant for testing.
2. Avoid multiple freeze-thaw cycles. A specimen should not be frozen and thawed more than twice prior to use with the MiraWell *H. pylori*.

GENERAL PREPARATION

1. Remove the Mylar pouch from the box.
2. Using the notched corners, tear open the Mylar pouch. Place all components on a clean, flat surface. Remove the cap from the Diluent Buffer vial (Red coloured cap) and place onto a clean, flat surface.
3. Ensure the blue Specimen Filtration Unit is placed firmly in the well of the white plastic Test Cartridge.

SPECIMEN COLLECTION

For Fingerstick Whole Blood:

1. Using the alcohol swab provided, clean the Index finger. Allow the finger to dry thoroughly.
2. Remove the plastic cap from the lancet and place the end against the clean site of the index finger. Puncture the skin by pressing down on the lancet. Hold the finger downward and apply gentle pressure beside the point of puncture.
3. Squeeze the outside of the disposable pipette and place it in the center of the blood drop. Slowly release the pressure to draw the blood into the channel of the pipette. Apply **one (1)** drop of blood into the uncapped Diluent Buffer vial (Red colour cap). Gently mix by tapping the bottom of the vial. Immediately begin the **TESTING PROCEDURE**.

For Serum, Plasma or Whole Blood:

1. Squeeze the outside of the disposable pipette and place it in the serum, plasma, or whole blood specimen. Slowly release the pressure to draw the specimen into the channel of the pipette.
2. Apply **one (1)** drop into the uncapped Diluent Buffer vial (red color cap) by placing the tip of the disposable pipette into the vial and gently squeezing the outside of the pipette. Gently mix by tapping the bottom of the vial. Immediately begin the **TESTING PROCEDURE**.

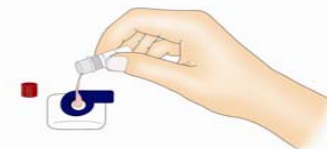
TESTING PROCEDURE

- All solutions must be completely absorbed into the test membrane before proceeding to the next step in the testing procedure.
- Once the test has been started, all subsequent steps should be completed without interruption.
- Perform the test on a flat work surface.
- Read the test results immediately. Failure to do so may result in inaccurate test results.

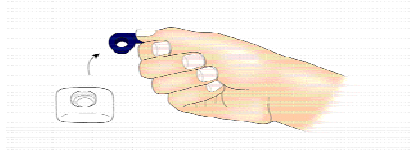
1. Apply **six (6)** drops of Universal Buffer to the center of the Blue Specimen Filtration Unit. Allow the buffer to absorb through the blue Specimen Filtration Unit completely.



2. Pour the entire contents of the Diluent Buffer vial (Red coloured cap) containing the specimen (as per SPECIMEN COLLECTION section) into the center of the blue Specimen Filtration Unit. Allow solution to completely absorb through the Specimen Filtration Unit before proceeding to the next step.



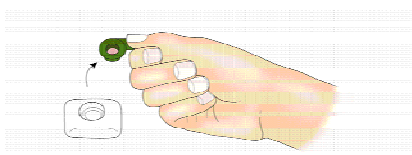
- Remove the blue Specimen Filtration Unit by gently twisting the handle in a circular and upwards motion.



- Place the InstantGold™ Cap (Green colour) loosely into the well of the test cartridge. Apply **twelve (12)** drops of Universal Buffer to the center of the Instant Gold™ Cap. Allow the buffer to absorb through the InstantGold™ Cap completely.



- Remove the InstantGold™ Cap by gently twisting the handle in a circular and upwards motion.



- To clarify the test result, add **three (3)** drops of Universal Buffer to the center of the test membrane. Allow the buffer to absorb through the membrane. **Read Test Results IMMEDIATELY**

QUALITY CONTROL

Built-in Control Features

MiraWell *H. pylori* includes a built-in procedural and reagent Control Line that demonstrates the validity of the testing procedure and reagent function. A vertical red line under the "C" (Control Area) on the test cartridge indicates that specimen has been added to the test cartridge, and that the test reagents are functioning properly. The Control Line will appear on all valid tests, regardless of whether the test result is Reactive or Non-Reactive (see **How to Read the Test Results** section).

HOW TO READ THE TEST RESULTS

NON-REACTIVE TEST RESULT

Probable Non-Exposure to *H. pylori*

The presence of one red line in the control region (C) means that the individual has probably not been exposed to *H. pylori*. If there is reason for concern, the individual should repeat the test within three to six months or consult a doctor.



REACTIVE TEST RESULT

Probable Exposure to *H. pylori*

The presence of two red lines in both the test region (T) and control region (C) means that the individual might be exposed to *H. pylori*. One line may be lighter than the other, and they do not have to match. It means that *H. pylori* antibodies are probably present in the individual's blood and he/she should visit the doctor as soon as possible.



INVALID TEST RESULT

The result is invalid if no red line appears in the control region (C), even if a line appears in the test region (T). Also, the presence of a broken line under the (C) indicates that there has been a problem, either with the test device or the specimen, during the Testing Procedure. The test procedure should be repeated with a new **MiraWell *H. pylori***. If the problem persists, contact your local distributor.



LIMITATIONS OF THE TEST

- This test must be used in accordance with this package insert to ensure accurate results.
- This test is for use only with serum, plasma or whole blood specimens. Use of other types of specimens may yield inaccurate test results.
- Test results are to be read and interpreted **immediately** upon completion of the test procedure. A delay in reading test results may yield inaccurate results.
- MiraWell *H. pylori*** is intended to be used as an aid in the diagnosis of infection with *H. pylori*.
- Specimens that do not pass through the membrane within thirty (30) seconds may be unsuitable for testing.
- The intensity of the red line (Reactive test result) does not necessarily correlate with the antibody titre of the specimen.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

Sensitivity studies were performed using *H. pylori* antibody positive specimens from 86 individuals at one testing site in North America. The rapid test was found to be 94.2% sensitive with 81 testing reactive with the rapid *H. pylori* test of the 86 confirmed reactive specimens.

SPECIFICITY

The overall specificity of the rapid test was 88.7% when 124 *H. pylori* negative specimens were tested.

PRODUCT WARRANTY

MedMira Laboratories Inc. guarantees the quality of this product if stored and used as instructed. Any component of the test found to be defective shall be replaced free of charge upon return of the defective product. MedMira Laboratories Inc. disclaims any implied warranty of merchantability or fitness for a particular purpose, and in no event shall MedMira Laboratories Inc. be liable for consequent damage.

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