

Package Insert

INTENDED USE

The MiraWell® Rapid HIV Test (MiraWell® HIV) is a single use, qualitative immunoassay for the detection of antibodies to the Human immunodeficiency virus (HIV) 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 HIV.

INTRODUCTION

At least two human immunodeficiency retroviruses (HIV-1 and HIV-2) are known to cause Acquired Immunodeficiency Syndrome (AIDS). HIV is transmitted mainly by unprotected sexual intercourse, direct exposure to blood or blood products, sharing needles among IV drug users, or from an HIV infected mother during the birthing process as well as through breastfeeding. Anyone exposed to HIV (HIV-1 and/or HIV-2) will produce antibodies, which are indicators of HIV infection. The detection of such antibodies represents a HIV positive test result (indicating that the individual is HIV-infected), but is not necessarily a diagnosis of AIDS. The absence of antibodies at the time of testing (indicating that the individual is not HIV-infected) is indicated by an HIV negative test result but does not totally rule out infection with HIV. It may take up to three months to develop antibodies to HIV after exposure.

The MiraWell® Rapid HIV Test (MiraWell HIV) is a rapid, flow-through device developed and manufactured by MedMira Laboratories (CANADA). This test qualitatively detects the presence of antibodies to HIV-1 and/or HIV-2 in serum, plasma, and whole blood specimens. The simple testing procedure of MiraWell HIV involves placing a drop of the whole blood sample through the pre-filter onto the coated test membrane and allowing it to flow through the membrane. If the sample contains HIV-1 and/or HIV-2 antibodies, they are captured on the test membrane and result in a highly specific antigen-antibody complex. The test result is visualized at a coloured end point through a reaction with a proprietary detection agent and can be interpreted immediately.

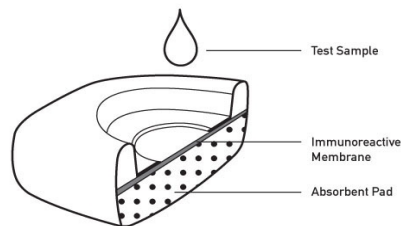


Figure 1: MedMira's Rapid Flow-Through Technology Platform

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, **is not** required to perform MiraWell HIV.

CONTENTS

Each box contains the following:

- 50 Mylar pouches each containing:
 - 1 test cartridge with blue Specimen Filtration Unit
 - 1 InstantGold™ Cap (green colour)
- 1 poly-zipper bag containing 2 Universal Buffer dropper bottle (30mL each)

- 1 poly-zipper bag containing 50 Diluent Buffer Vials (red color cap)
- 1 poly-zipper bag containing 50 disposable pipettes

WARNINGS

1. Read this instruction sheet completely and carefully prior to use with MiraWell HIV. If the directions are not followed exactly, inaccurate test results may occur.
2. Perform MiraWell HIV on a flat work surface to ensure reagents and specimen 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 HIV as directed by governing infectious waste guidelines.
5. Sodium azide is used as a preservative in the MedMira Universal Buffer and diluent 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, green conjugate cap, blue specimen filtration unit, and disposable pipette only once and dispose of properly. **Do not reuse these components.**
2. Do not touch 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 all test materials with care after use

DIRECTIONS FOR USE

Specimen Collection

1. MiraWell HIV 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 MiraWell HIV.

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 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.

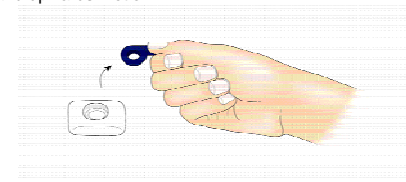
1. Apply **six (6)** drops of Universal Buffer to the center of the Blue Specimen Filtration Unit. Allow the buffer to absorb through the blue Specimen Filtration Unit completely.



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.



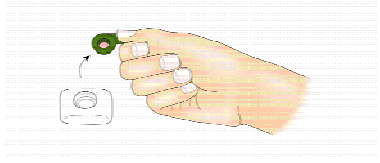
3. Remove the blue Specimen Filtration Unit by gently twisting the handle in a circular and upwards motion.



4. 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.



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



6. 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 HIV test 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 HIV-1 and/or HIV-2

The presence of one red line in the control region (C) means that the individual has probably not been exposed to HIV-1 and/or HIV-2 but does not exclude the possibility of exposure to, or infection with HIV-1/2. Following a recent exposure to HIV, it may take several months for the antibody response to reach detectable levels. If there is reason for concern, the test should be repeated within three to six months or consult a doctor.



REACTIVE TEST RESULT

Probable Exposure to HIV-1 or HIV-2

The presence of two red lines in both the test region (T) and control region (C) means that the individual might be exposed to HIV-1 and/or HIV-2. One line may be lighter than the other, and they do not have to match. It means that HIV-1 and/or HIV-2 antibodies are probably present in the individual's blood and he/she should visit the doctor as soon as possible. All reactive test results **should** be confirmed and evaluated with respect to an overall clinical evaluation before a diagnosis is made.



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 HIV* test. If the problem persists, contact your local distributor.



LIMITATIONS OF THE TEST

1. This test must be used in accordance with this package insert to ensure accurate results.
2. This test is for use only with serum, plasma or whole blood specimens. Use of other types of specimens may yield inaccurate test results.
3. 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.
4. *MiraWell*® HIV is intended to be used as an aid in the diagnosis of infection with HIV.
5. Specimens that do not pass through the membrane within thirty (30) seconds may be unsuitable for testing.
6. 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 HIV-1 antibody positive specimens from 582 individuals who tested Western Blot positive for HIV. The rapid HIV tests were reactive with 580 of the 582 for a sensitivity of 99.7%. The rapid HIV test was found to be 100% sensitive when 54 various clades of HIV-1 group M, 10 HIV-1 group O, and 299 HIV-2 specimens were tested (Table 1). The sensitivity of the rapid HIV test was **99.7%** when 1512 Western blot confirmed positive specimens (different clades) were tested (Table 2).

Table 1. Sensitivity with HIV-1 group M, group O, and HIV-2

Specimen (group, clade)	Number of Specimens	Sensitivity
HIV-1 (M, A)	10	100%
HIV-1 (M, B)	10	100%
HIV-1 (M, C)	11	100%
HIV-1 (M, D)	5	100%
HIV-1 (M, E)	3	100%
HIV-1 (M, F)	3	100%
HIV-1 (M, G)	2	100%
HIV-1 (O)	10	100%
HIV-2	299	100%

Table 2. Sensitivity with HIV-1 Clades by Region

Country	Prevalence	Number of Specimens	Sensitivity
Canada	B	836	99.8%
India	C, A, B	20	100%
Peru	B, F	20	100%
Tanzania	C, A, D	14	100%
Thailand	E, B	20	100%
Trinidad	B	20	100%
United States	B	582	99.7%

SPECIFICITY

The overall specificity of the rapid HIV test was **99.7%** when 11,216 negative specimens were tested.

REACTIVITY WITH SEROCONVERSION PANELS

Thirty seroconversion panels were tested in comparison to licensed anti-HIV-1,2 EIA. Each panel consisted of a series of sequential specimens obtained from a single individual undergoing seroconversion. The 30 seroconversion panels consisted of 143 specimens. In this study, the rapid HIV test detected seroconversion similarly to the licensed HIV-1,2 EIA.

REACTIVITY WITH LOW TITRE HIV-1 ANTIBODY PERFORMANCE PANELS

A low titre HIV-1 antibody panel consisting of 15 specimens, obtained from a commercial source, was tested in comparison with licensed anti-HIV EIA tests. The rapid HIV test was capable of detecting antibodies to HIV-1 similarly to the licensed anti-HIV EIA tests.

INTERFERENCE STUDIES

Interference studies were carried out on 1220 specimens, the results indicate that EDTA, heparin, sodium citrate, abnormal levels of chemistry markers (i.e. alkaline phosphatase, alanine aminotransferase, lactate dehydrogenase, thyroid stimulating hormone, glucose, cholesterol, amylase, and various ions), seromarkers associated with unrelated medical condition (i.e. rheumatoid factor, infectious mononucleosis, *Helicobacter pylori*, hepatitis A, B, or C, herpes simplex virus, mycoplasma, mumps, measles, rubella, and syphilis), and specimens obtained from pregnant women did not interfere with the test.

REPEATABILITY AND REPRODUCIBILITY

Three blind coded panels were tested with three lots of the test, on three testing days at three sites. Results of these studies indicated 100% repeatability and reproducibility.

EQUIVALENCE OF ANALYTES

When serum, plasma, and whole blood was collected from the same individual and tested with the rapid HIV test 100% correlation was observed between the three analytes and a reference test (EIA).

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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