revealHIV
rapid HIV test

The Reveal® Rapid HIV Test (Reveal HIV) is a rapid vertical flow test developed and manufactured by MedMira Laboratories Inc. The test qualitatively detects the presence of antibodies to HIV-1 and/or HIV-2 in serum, plasma, or whole blood specimens.

Reveal HIV (Point of Care) **815311000577** ***(for Fingerstick Whole Blood)*** ***Includes a test tray in each pouch***	**Reveal HIV (LAB +)** **815311000607** ***(For Venipuncture Whole Blood/Serum/Plasma)***	**Reveal HIV (LAB S/P)** **815311000690** ***(For Serum/Plasma)***
20 Mylar pouches each containing: 1 test cartridge 1 InstantGold cap 1 silica gel packet 1 auto-fill pipette 1 Universal Buffer vial 1 1 Universal Buffer vial 2 1 lancet (sterile) 1 alcohol swab 1 package insert 1 lancet use card	50 Mylar pouches each containing: 1 test cartridge 1 InstantGold cap 1 silica gel packet 2 bottles Universal Buffer 50 transfer pipettes 50 sample tubes 1 package insert	50 Mylar pouches each containing: 1 test cartridge 1 InstantGold cap 1 silica gel packet 2 bottles Universal Buffer 50 transfer pipettes 1 package insert

INTENDED USE

Reveal HIV is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus (HIV) Type 1 and Type 2 in human serum, plasma, or whole blood. Reveal HIV is intended for use by healthcare professionals as an aid in the diagnosis of infection with HIV-1 and/or HIV-2.

TEST DESCRIPTION

Reveal HIV is a manually performed, visually interpreted, rapid vertical flow immunoassay. The test cartridge contains an immunoreactive test membrane comprised of specially formulated synthetic peptides to gp36, gp41, gp120 and HIV-1 group O, coated onto a membrane matrix, which functions to capture anti-HIV-1/2 antibodies present in human serum, plasma and whole blood when a drop of the specimen is applied. In addition, the test membrane has a procedural and reagent Control Line comprised of an optimized amount of protein A. Following the application of the sample, captured anti-HIV-1/2 antibodies are visualized through a reaction with the InstantGold cap, which contains a proprietary protein A-colloidal gold conjugate.

WARNINGS AND SAFETY RECOMMENDATIONS

1. **The test is intended for *in vitro* diagnostic use by healthcare professionals. This product is not to be used for self-testing.**
2. **Read this instruction sheet completely and carefully prior to use of this test. If the directions are not followed exactly, inaccurate test results may occur.**
3. Handle specimens, and all materials contacting specimens as if capable of transmitting infectious agents.
4. Do not smoke, eat, or drink in areas where specimens or test reagents are handled. Do not pipette by mouth.
5. Wear disposable gloves, laboratory coat and eye protection throughout the test procedure.
6. Dispose of all test specimens and materials used in the test as directed by governing infectious waste guidelines.

HANDLING PRECAUTIONS

1. Use test components only once, excluding the bottles of Universal Buffer in LAB+ and LAB S/P products, and dispose of properly. Once opened, the bottles of Universal Buffer are stable throughout the expiration period of the product.
2. Do not touch the immunoreactive test membrane. Touching the membrane may compromise test results.
3. Store in a dry place at 2 - 30°C.
4. Exercise care in handling test components to prevent contamination.
5. Adequate lighting is required to read the test results.
6. Ensure that the Mylar pouch is intact and that the expiration date printed on the outside of the pouch is valid. If the pouch is not intact or is expired, discard and obtain a new pouch.
7. Allow the components to equilibrate to room temperature for 30-60 minutes before performing the test.
8. Keep the test cartridges and reagents in sealed packages until immediately prior to use. Using the notched corners, tear open the pouch and remove the components, placing them on a clean, flat surface.

SPECIMEN HANDLING & COLLECTION

Serum/Plasma Collection (Cat. # 815311000607 or 815311000690)

1. Plasma obtained using EDTA, heparin or sodium citrate as anticoagulants is suitable for testing.
2. Fresh specimens may be tested immediately upon receipt or stored at 2-8°C for up to 5 days prior to testing. If storage is necessary for more than 5 days, serum or plasma specimens should be stored at - 20°C or below.
3. Particulate matter can block the test membrane or cause high background making interpretation of results difficult. Cloudy or viscous specimens should not be used for testing.
4. 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 capped tube.
   b. Centrifuge an aliquot of the specimen in a small, capped tube at room temperature (15-27°C) at 3361 g (radius of rotor 8.35 cm = 6000 rpm) for at least 5 minutes and use only the clear supernatant for testing.
5. Avoid multiple freeze-thaw cycles. A specimen should not be frozen and thawed for more than twice prior to use with this test.

Venipuncture Whole Blood Collection and Use (Cat. # 815311000607)

1. Use standard venous phlebotomy procedures to collect a whole blood sample. If specimens are not tested at the time of collection, they may be stored at 2 - 8°C for up to five (5) days prior to testing. If storage is necessary for over five (5) days, plasma should be separated from the whole blood specimen and the plasma should be stored at -20°C or below.
2. Place the sample tube in a secured rack on a flat surface and add five (5) drops from the bottle of Universal Buffer to the sample tube.
3. Using the transfer pipette provided, collect whole blood from the specimen collection tube. Add one (1) drop of whole blood to the sample tube prepared in Step 2.
4. Hold the sample tube and gently tap the side of the tube near the bottom until the mixture becomes a clear reddish colour.
5. Proceed to TEST PROCEDURE.

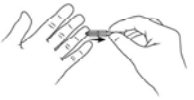
Fingerstick Whole Blood Collection and Use
(Cat. # 815311000577)

1. Uncap and place Universal Buffer vial 1 into the hole of the test tray.

2. Using an alcohol swab, clean the index finger. Allow the finger to dry thoroughly.

3. Using the lancet provided with the test, lance the fingertip in preparation for collection of the fingerstick whole blood specimen. Refer to Lancet use card included in the box for detailed instructions.

4. Use the auto-fill pipette provided to collect a drop of blood from the fingerstick site. To do this, touch the tip of the pipette to the blood sample in a horizontal position. The blood sample will be automatically drawn to the black fill line and stop. **Do not** squeeze the pipette bulb during filling.



5. Place the tip of the auto-fill pipette into the Universal Buffer in Universal Buffer vial 1. Squeeze the bulb to empty the blood sample into the vial. Discard the auto-fill pipette. Recap Universal Buffer vial 1.

6. Hold Universal Buffer vial 1 and gently tap the side of the vial near the bottom until the mixture becomes a clear reddish colour.

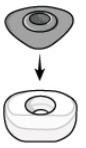
7. Proceed to TEST PROCEDURE.

TEST PROCEDURE

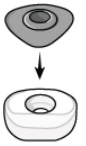
Important Notes:

- Check the Reveal HIV catalogue number and select corresponding procedure.
- All solutions must be completely absorbed into the test membrane before proceeding to the next step in the test procedure.
- Once the test has been started, all subsequent steps should be completed without interruption.
- Perform the test on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.
- Read the test results immediately. Failure to do so may result in inaccurate test results.

FINGERSTICK WHOLE BLOOD PROCEDURE (Cat. No. 815311000577)

1	2	3
		
Pour the entire contents of Universal Buffer vial 1 into the center of the test cartridge. Allow the specimen to absorb completely.	Place the InstantGold cap on the test cartridge	Pour the entire contents of Universal Buffer vial 2 onto the InstantGold cap and allow the solution to absorb completely. Remove the InstantGold cap and wait for the solution to absorb completely. Read test results immediately.

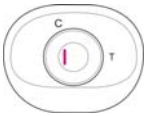
VENIPUNCTURE WHOLE BLOOD PROCEDURE (Cat. No. 815311000607)

1	2	3
		
Pour the entire contents of the sample tube into the center of the test cartridge. Allow the specimen to absorb completely.	Place the InstantGold cap on the test cartridge	Dispense twelve (12) drops of Universal Buffer onto the InstantGold cap and allow the solution to absorb completely. Remove the InstantGold cap and wait for the solution to absorb completely. Add three (3) drops of Universal Buffer to clarify results. Read test results immediately.

SERUM/PLASMA PROCEDURE (Cat. No. 815311000607 OR Cat. No. 815311000690)

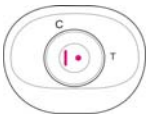
1	2	3
		
Apply three (3) drops of Universal Buffer to the center of the test cartridge. Allow the buffer to absorb completely.	Apply one (1) drop of serum or plasma to the center of the test cartridge. Allow the specimen to absorb completely. If the serum or plasma specimen is not absorbed within 30 seconds, centrifuge an aliquot of the specimen in a small, capped tube at room temperature (15 - 27°C) at 3361 x g (radius of rotor 8.35 cm = 6000 rpm) for at least five (5) minutes. Test the clear supernatant using a new test cartridge. If slow absorption persists after centrifu-	Place the InstantGold cap on the test cartridge. Dispense twelve (12) drops of Universal Buffer onto the InstantGold cap and allow the solution to absorb completely. Remove the InstantGold cap and wait for the solution to absorb completely. Add three (3) drops of Universal Buffer to clarify results. Read test results immediately.

TEST RESULTS



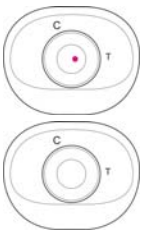
Non-Reactive Test Result
Probable Non-Exposure to HIV-1 and/or HIV-2

The presence of a vertical red line under the **C** means that individual has probably not been exposed to HIV-1 and/or HIV-2 but does not exclude the possibility of exposure to HIV. Following an 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 3 to 6 months or consult a healthcare provider.



Reactive Test Results
Probable Exposure to HIV-1 and/or HIV-2

The presence of both a vertical red Control Line under the **C** and a red dot beside **T** on the test, regardless of intensity, means the individual might have been exposed to HIV-1 and/or HIV-2. This means that HIV-1 and/or HIV-2 antibodies are probably present in the individual's blood and he/she should seek medical care as soon as possible. Any visible dot beside **T** on the test must be considered to be a Reactive result. All Reactive test results should be confirmed and evaluated with respect to overall clinical evaluation before a diagnosis is made.



Invalid Test Results

The result is Invalid if no red line appears under the **C**, even if a dot appears beside **T** on the test. Also, the presence of a broken line under the **C** indicates that there has been a problem, either with the test or the specimen, during the Test Procedure. The Test Procedure should be performed again with a new Reveal HIV test. If the problem persists, contact MedMira Customer Support.

QUALITY CONTROL

It is the responsibility of the user to establish an adequate quality assurance program to ensure the proper performance of this rapid test under its conditions of use.

Built-in Control Features

This rapid 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 Zone) 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 **Test Results** section).

LIMITATIONS OF THE TEST

1. The test must be used in accordance with this package insert to ensure accurate results.
2. The test is for use only with serum, plasma, or whole blood specimens. Use of other types of specimens may yield inaccurate 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. Serum or plasma specimens that do not pass through the membrane in 30 seconds, may be unsuitable for testing.
5. A Reactive test result suggests the presence of anti-HIV antibodies in the specimen.
6. The intensity of the red dot (Reactive test result) does not necessarily correlate with the antibody titre of the specimen.
7. A Non-Reactive test result indicates the absence of detectable antibodies to HIV in the specimen but does not exclude the possibility of exposure to, or infection with HIV.
8. All Reactive test results should be confirmed and evaluated with respect to an overall clinical evaluation before a diagnosis is made.

PERFORMANCE CHARACTERISTICS

Sensitivity

Sensitivity studies were performed using HIV-1 antibody positive specimens. The sensitivity of the rapid HIV test was 99.8% when 1967 Western blot confirmed positive specimens (different clades) were tested (Table 1). The rapid HIV test was found to be 100% sensitive when 44 specimens of various clades of HIV-1 group M, 10 HIV-1 group O specimens, and 299 HIV-2 specimens were tested (Table 2).

Table 1: Sensitivity with HIV-1 Clades by Region

Country	Prevalence	Number of Specimens	Sensitivity
Canada	B	836	99.8%
India	C,A,B	20	100%
Kenya	C,A	205	100%
Peru	B,F	20	100%
South Africa	C	250	100%
Tanzania	C,A,D	14	100%
Thailand	E,B	20	100%
Trinidad	B	20	100%
United States	B	582	99.7%
TOTAL		**1967**	**99.8%**

Table 2: 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%

Specificity

The overall specificity of the rapid HIV test was 99.7% when 11,669 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 219 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.

REFERENCE DOCUMENTS

1. Operational characteristics of commercially available assays to detect antibodies to HIV-1 and/or HIV-2 in human sera. Report 9/10. World Health Organization, Geneva. January 1998.
2. Centre for Emergency Preparedness and Response, Health Canada. 2004. Third edition. Laboratory Biosafety Guidelines.
3. World Health Organization. 2004. Laboratory biosafety manual. Third edition. Geneva.
4. CDC. Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive procedures. MMWR Recommendations and Reports. 1991, 40 (RR-08) 1-9
5. Whidmer, A.F. & R. Frei. 2003. "Decontamination, Disinfection and Sterilization. In: Murray PR, ed. Manual of Clinical Microbiology. 9th edition. ASM Press. 2007. pp 65-96.
6. CDC. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. MMWR Recommendations and Reports. 2006, 55 (RR-14).

Explanation of Symbols

	Temperature Limit		Use by
	Manufacturer		Do not reuse
REF	Catalogue number	IVD	*in vitro* diagnostic medical device
LOT	Lot number		Consult instructions before use
EC REP	Authorized Representative in the European Community	CE	CE Marking of Conformity

EC REP

EU Auth. Rep.
Advena Ltd.
Pure Offices, Plato Close
Warwick, CV34 6WE, UK

CE 0318

MedMira Laboratories Inc.
155 Chain Lake Drive, Suite 1
Halifax, NS B3S 1B3 CANADA
T. 1 902 450 1588
E. support@medmira.com
www.medmira.com