Alert: Changes to the product format, including the addition of a Procedural and Reagent Control Line for the *Reveal*™ G2 Rapid HIV-1 Antibody Test, were recently approved by the United States FDA. Please be aware that product lot numbers REIAXXXX and following are the latest version of the product, and that the TEST PROCEDURE and the INTERPRETATION OF TEST RESULTS will differ from the previous lot numbers REIA0001-REIA00XX.

This package insert must be read carefully and completely prior to use of the *Reveal*™ G2 Rapid HIV-1 Antibody Test. Instructions must be followed carefully. If directions are not followed exactly, inaccurate test results may occur.

Complexity: Moderate

NAME AND INTENDED USE

The *Reveal*™ G2 Rapid HIV-1 Antibody Test is a single use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in human serum or plasma. The *Reveal*™ G2 Rapid HIV-1 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid tests are available, this test should be used in appropriate multi-test algorithms.

RESTRICTIONS

- **Sale of the *Reveal*™ G2 Rapid HIV-1 Antibody Test is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.**
- **The *Reveal*™ G2 Rapid HIV-1 Antibody Test is approved for use only by an agent of a clinical laboratory.**
- **Test subjects must receive the "Subject Information Brochure" prior to specimen collection, and appropriate information when test results are provided.**
- **The *Reveal*™ G2 Rapid HIV-1 Antibody Test is not approved for use to screen donors of blood, plasma, cells or tissues.**

SUMMARY AND EXPLANATION OF THE TEST

Human Immunodeficiency Virus (HIV) causes Acquired Immune Deficiency Syndrome (AIDS). Of the two types of HIV (HIV type 1 and HIV type 2), HIV-1 is far more prevalent within North America and in most regions worldwide. HIV is known to be transmitted through contact with the body fluids of an infected individual. Sexual contact, exposure to blood through contaminated syringes and needles or transfusion, or from an infected mother during the birthing process or through breastfeeding are the major modes of HIV transmission.

Infection with HIV-1 and/or HIV-2 elicits an immune response resulting in the production of corresponding anti-HIV antibodies. Antibody detection tests for HIV-1/HIV-2 antibodies provide a means to aid in the diagnosis of HIV-infected individuals [1,2]. However, when utilizing HIV antibodies to diagnose HIV infection, corresponding clinical factors must also be considered. Following a recent exposure to HIV, it may take several months for the antibody response to reach detectable levels, during which time testing for antibodies to HIV will not be indicative of true infection status. On the other hand, newborns of HIV-infected mothers may carry maternal antibodies to HIV for up to eighteen months, which may not necessarily indicate the true infection status of the newborn.

Conventional laboratory testing for antibodies to HIV utilizes enzyme immunoassays (EIAs) followed by confirmation of repeatedly reactive EIAs using supplemental tests such as the Western blot test, both of which are complex, multi-step procedures. Rapid immunoassay technology has proven to be extremely useful in the diagnosis of infection and is widely utilized as a screening tool. Although use of an EIA screening test is well-suited for batch testing, the turnaround time could be several days to a few weeks. Additionally, the complexity and cost of EIA screen testing and the required equipment may prohibit its universal utilization in medical settings with limited resources and personnel.

Rapid, less complex HIV testing could improve the delivery of medical care and HIV prevention services with substantial time and cost savings [3,4]. Realizing the utility of rapid tests, the World Health Organization (WHO) recommends the use of alternative testing strategies using rapid and simpler HIV tests [5]. Similar recommendations were made by the United States Centers for Disease Control and Prevention (CDC) upon determining that large numbers of patients tested for HIV using conventional methods did not return to the medical facility to obtain test results. From a public health perspective, this high non-return rate has great implications for the health and welfare of an HIV-infected individual and his/her contacts [6]. The *Reveal*™ G2 Rapid HIV-1 Antibody Test is a rapid, flow-through diagnostic immunoassay developed to utilize the performance characteristics of a conventional diagnostic immunoassay while simplifying the testing procedure to eliminate the requirement for expensive equipment and highly trained personnel and decrease turnaround time.

BIOLOGICAL PRINCIPLES OF THE TEST

The *Reveal*™ G2 Rapid HIV-1 Antibody Test is a manually performed, visually interpreted, rapid immunoassay. The *Reveal*™ G2 Rapid HIV-1 Antibody Test is comprised of a single-use test cartridge containing an immunoreactive test membrane. The immunoreactive test membrane is comprised of a combination of synthetic peptides corresponding to conserved regions of HIV structural proteins coated onto a membrane matrix, which functions to capture anti-HIV-1 antibodies present in human serum or plasma when a drop of the specimen is applied. In addition, the test membrane has a procedural and reagent Control Line comprised of protein A. Following the application of the sample, the membrane is washed with MedMira Universal Buffer to remove any non-specifically bound antibodies. Captured anti-HIV-1 antibodies are visualized through a reaction with the MedMira Colorimetric Detection Agent (a proprietary protein A-colloidal gold conjugate) followed by a second washing step with MedMira Universal Buffer for clarification of the test result. A Reactive test result occurs only when the protein A portion of the conjugate binds to the captured antibodies, producing a distinctive red dot in the test (T) zone and a vertical red Control Line in the control (C) zone of the test membrane upon completion of the test procedure. In contrast, a Non-Reactive test result, due to the absence of the HIV-1 antibody/antigen complex, is indicated by the presence of only the vertical red Control Line on the test membrane. If the vertical red Control Line is not present, the test result is considered invalid and testing must be repeated with a new cartridge (refer to *Test Results and Interpretation of Results* section below).

The test results are to be read and interpreted **immediately** following the final washing step with Universal Buffer. Precision pipetting, sample manipulation or specialized equipment **are not required** to perform the *Reveal*™ G2 Rapid HIV-1 Antibody Test.

MATERIALS PROVIDED

The *Reveal*™ G2 Rapid HIV-1 Antibody Test (Figure 1) is a unitized, ready-to-use test device that is packaged with all required test components in two configurations. One box contains the following:

Component	Quantity for Catalogue # 815311000232	Quantity for Catalogue # 815311000249
Test Cartridge Mylar pouch Each pouch contains: Test Cartridge (1) Disposable Pipette (1) Desiccant packet (1)	60	20
MedMira Colorimetric Detection Agent Mylar pouch; Each pouch contains: • 1 vial of lyophilized colorimetric detection agent comprised of protein A conjugated to colloidal gold in a buffered solution (Preservative: 0.1% sodium azide) • Desiccant packet (1).	4	2
MedMira HIV-1 Human Test Control Mylar pouch; Each pouch contains: • 1 vial of MedMira Positive Test Control* (lyophilized, heat-inactivated human serum/plasma positive for HIV-1 antibodies and negative for Hepatitis B surface antigen and Hepatitis C antibodies, in a buffered solution). • 1 vial of MedMira Negative Test Control* (lyophilized human serum/plasma negative for HIV antibodies and antigen, Hepatitis B surface antigen, and Hepatitis C antibodies, in a buffered solution). • Desiccant packet (1) * MedMira HIV-1 Human Test Controls do not contain preservative	1	1
A 4"x6" poly zipper bag containing: • One drop dispenser bottle containing 30 mL of **MedMira Universal Buffer** solution, composed of Tris-buffered saline, synthetic polymers and an anti-microbial agent (Preservative: 0.1% sodium azide). • One screw-capped bottle containing 30 mL of **MedMira Universal Buffer** solution. Disposable Pipettes One 3"x8" poly zipper bag containing Calibrated Transfer Pipettes	1 1 1 box containing 60 pipettes 4 pipettes	1 1 1 poly zipper bag containing 20 pipettes 2 pipettes
Package Insert	1	1
Subject Information Brochure	60	20
Customer Letter	1	1

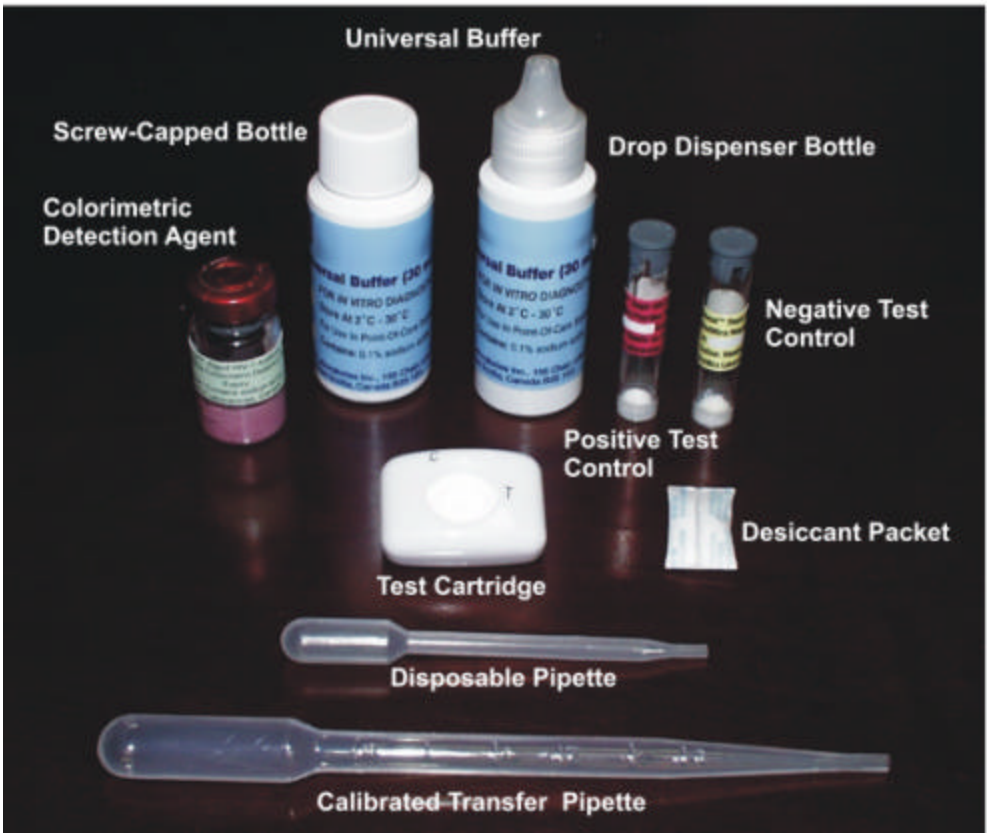


Figure 1. Components of the *Reveal*™ G2 Rapid HIV-1 Antibody Test

MATERIALS PROVIDED AS AN ACCESSORY TO THE TEST
Additional components may be purchased from MedMira's Sales and Marketing Department, subject to availability.

Component	Description*	Catalogue Number
MedMira Universal Buffer	One 30 mL Drop Dispenser bottle One 30 mL Screw-Capped bottle	1009785RDB 1009785RSB
MedMira Colorimetric Detection Agent	1 Mylar pouch containing 1 vial of Colorimetric Detection Agent	1009785RCG
MedMira HIV-1 Human Test Controls	1 Mylar pouch containing 1 Positive and 1 Negative Test Control	1009785RCP
Disposable Pipettes	1 poly zipper bag containing 20 pipettes	1009785RPI
Calibrated Transfer Pipettes	1 poly zipper bag containing 2 Calibrated Transfer Pipettes	1009785RRP

*Component's description is exactly as described in **Materials Provided** section above.

MATERIALS REQUIRED BUT NOT PROVIDED
1. Disposable gloves
2. Laboratory coat
3. Biohazard waste disposal bags suitable for autoclaving
4. Permanent marking pen
5. Disinfectant (household bleach)
6. Liquid waste discard container with a freshly prepared 0.5% solution of sodium hypochlorite (10% solution of household bleach)

WARNINGS
For *In Vitro* Diagnostic Use
1. **Read the package insert completely and carefully prior to use of the *Reveal*™ G2 Rapid HIV-1 Antibody Test. If the directions are not followed exactly, inaccurate test results may occur.**
2. **The United States Food and Drug Administration has approved this test for use with serum or plasma specimens only. Use of this test with specimens other than those specifically approved for use with the *Reveal*™ G2 Rapid HIV-1 Antibody Test may result in inaccurate test results.**
3. **Perform the *Reveal*™ G2 Rapid HIV-1 Antibody Test at room temperature (15-27°C).**
4. **Perform the *Reveal*™ G2 Rapid HIV-1 Antibody Test on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.**

PRECAUTIONS

Safety Precautions

1. Handle specimens, MedMira HIV-1 Human Test Controls, and all materials contacting specimens as if capable of transmitting infectious agents. It is recommended that all specimens and test reagents be handled in accordance with biosafety level 2 practices as described in Laboratory Biosafety Guidelines, Health Canada[7], the CDC/NIH publication on Biosafety in Microbiological and Biomedical Laboratories[8], WHO biosafety manual[9] or CDC Universal Precautions[10].
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, laboratory coat and eye protection throughout the test procedure. Upon completion of the test, gloves must be treated as biohazardous waste and disposed of accordingly. Wash hands thoroughly after disposing of gloves.
4. Wipe spills promptly with a 1% sodium hypochlorite solution (five-fold v/v dilution of household bleach, prepared fresh daily) or other appropriate disinfectant[11]. Contaminated materials should be disposed of as biohazardous waste.
5. Add an equal volume of freshly prepared 5% sodium hypochlorite solution (household bleach) to liquid wastes and allow them to soak for at least 1 hour for disinfection.
6. Dispose of all test specimens and materials used in the *Reveal*™ *G2* Rapid HIV-1 Antibody Test in a biohazardous waste container. The recommended method of disposal is autoclaving for a minimum of 1 hour at 121^0 C or by incineration. **Note: Do not autoclave solutions that contain bleach.**
7. Sodium azide is used as a preservative in the MedMira Universal Buffer. Sodium azide forms lead or copper azide in laboratory plumbing and may explode on percussion, such as hammering. 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 and specimen pipette only once and dispose of properly (see *Safety Precautions*). **Do not reuse these components.**
2. **Do not touch the immunoreactive test membrane.**
3. Do not use the *Reveal*™ G2 Rapid HIV-1 Antibody Test or any of its components beyond the expiration date. The expiration date is printed on all labels. Always check the expiration date prior to testing. Reconstituted Test Controls are stable for up to seven (7) days, and reconstituted Colorimetric Detection Agent is stable for up to 30 (thirty) days when stored at 2 - 8°C.
4. Do not interchange reagents or devices from different lots.
5. To prevent contamination, do not interchange stoppers on the vials (MedMira Colorimetric Detection Agent and the MedMira HIV-1 Human Test Controls).
6. Exercise care in handling test components to prevent contamination.
7. Adequate lighting is required to read the test result.

STORAGE INSTRUCTIONS

Unopened *Reveal*™ G2 Rapid HIV-1 Antibody Tests should be stored in a dry area at 2 - 30^0 C.

Keep the test cartridges and reagents in sealed packages until use.

Following reconstitution, the MedMira HIV-1 Human Test Controls may be used or stored at 2 - 8°C for up to seven (7) days. Vials of MedMira Colorimetric Detection Agent should be reconstituted one at a time as required. Reconstituted Detection Agent may be stored at 2 - 8°C for up to thirty (30) days. Ensure that stoppers are secure during storage.

If tests and reagents are stored at refrigerated temperatures, allow all test components and specimens to equilibrate to room temperature (15-27°C) for 30-60 minutes prior to opening the packages.

DIRECTIONS FOR USE

A. Specimen Collection

1. The *Reveal*™ G2 Rapid HIV-1 Antibody Test can be used to test either serum or plasma 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 - 8^0 C for up to five (5) days prior to testing. Specimens should be stored at -20^0 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.**

B. Specimen Shipping

1. If specimens are to be shipped, dispatch by the fastest means available. Package specimens in compliance with statutory regulations governing transportation of dangerous goods.
2. Serum or plasma specimens may be shipped overnight at ambient temperature. However, if the transit time is expected to exceed 24 hours and/or the ambient temperature is >35^0C, specimens should be shipped at 2 - 8°C.

C. 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 *Reveal*™ G2 Rapid HIV-1 Antibody Test.

D. General Test Preparation

1. Provide the "Subject Information Brochure" to the test subject prior to specimen collection.
2. Allow all test components and specimens to equilibrate to room temperature (15-27°C) for 30-60 minutes prior to opening the container or Mylar pouch.
3. Using the notched corners, tear open the required number of Test Cartridge Mylar pouches. Ensure that a desiccant packet is present in each pouch. If the desiccant packet is not present, discard the test cartridge and open a new pouch.
4. Inspect each test cartridge to ensure that a faint blue line is visible in the Control zone (under the **C** on the test cartridge). If this blue line is not visible, discard the test cartridge and open a new pouch.
5. Align the test cartridges in front of the specimens to be tested. Label test cartridges on the white plastic casing with a permanent marking pen. **DO NOT LABEL OR MAKE ANY MARKS ON THE IMMUNOREACTIVE TEST MEMBRANE.**

E. Reconstitution of Reagents

I. MedMira Colorimetric Detection Agent

The MedMira Colorimetric Detection Agent should be reconstituted immediately prior to performing the test procedure.

1. Using the notched corners, tear open the required number of MedMira Colorimetric Detection Agent Mylar pouches. One (1) vial of MedMira Colorimetric Detection Agent is packaged in each Mylar pouch, and is sufficient to perform fifteen (15) individual tests. To determine the number of vials of Colorimetric Detection Agent required, use the following formula:

$$\frac{\text{(number of specimens (including test controls if required))}}{15} = \text{number of vials to reconstitute, rounding up to a whole number}$$

2. Carefully tear off the metal closure(s) and remove the stopper(s) from the vial(s) of the MedMira Colorimetric Detection Agent.
3. Remove the cap from the screw-capped bottle of MedMira Universal Buffer. Squeeze the bulb of a calibrated transfer pipette (contained in the poly zipper bag labelled Calibrated Transfer Pipettes) between the thumb and the index finger. Place the tip of the calibrated pipette into the opened Universal Buffer bottle. Slowly release the pressure in the bulb to draw the Universal Buffer into the channel of the pipette to the 2 mL mark. Transfer all of the contents of the pipette into one vial of Colorimetric Detection Agent. Replace the stopper tightly. Repeat this step for each vial required, calculated in step 2 above.
4. Gently mix each vial, one at a time, by tapping the bottom of the vial until all material has dissolved. **Do not mix by inverting the vial** as this will cause excess foaming.
5. After mixing, ensure that the solution is a rose pink colour and free of precipitate by visual inspection. If the solution is blue or if precipitate is present, discard the solution and reconstitute another vial using steps 2-6 described above. If the problem recurs, contact the MedMira Sales and Marketing Department for replacement.
6. Note the dates of reconstitution and expiration (thirty (30) days later) on the vial with a permanent marking pen and store the remaining reconstituted MedMira Colorimetric Detection Agent upright in the stoppered vial at 2 - 8°C for up to thirty (30) days.
7. Discard remaining reconstituted reagents not used within thirty (30) days. The MedMira Colorimetric Detection Agent can be disposed of in the sink and flushed with water.

II. MedMira Positive and Negative Test Controls

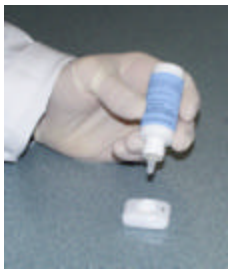
MedMira HIV-1 Human Test Controls should be reconstituted immediately prior to performing the test procedure.
One (1) vial contains sufficient quantity to perform five (5) tests.

1. Using the notched corners, tear open a *MedMira HIV-1 Human Test Control* Mylar pouch.
2. Remove the vial of MedMira Negative Test Control and carefully remove the stopper.
3. Hold the MedMira Universal Buffer bottle on a slight angle from vertical (See **Testing Procedure** section) directly above the vial to avoid air bubbles. Add six (6) drops of MedMira Universal Buffer through the buffer bottle drop dispenser tip by gently squeezing the bottle.
4. Replace the stopper tightly, and gently mix by tapping the bottom of the vial until all material has dissolved. **Do not mix by inverting the vial** as this will cause excess foaming.
5. After mixing, the solution should be clear with a slight yellow tint. If this is not the case, contact the MedMira Sales and Marketing Department for replacement.
6. Repeat steps 2-5 above with the MedMira Positive Test Control.
7. Note the dates of reconstitution and expiration (seven (7) days later) on the vials with a permanent marking pen. Store the remaining reconstituted MedMira HIV-1 Human Test Controls upright in the stoppered vials at 2 - 8°C for up to seven (7) days.
8. Discard remaining reconstituted reagents not used within seven (7) days. The MedMira HIV-1 Human Test Controls should be treated as liquid infectious waste and be disposed of according to local guidelines. The recommended method of disposal is autoclaving for a minimum of 1 hour at 121^0 C or by incineration.

F. Testing Procedure

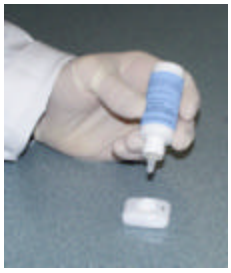
- ***All solutions must be completely absorbed into the test membrane before proceeding to the next step in the testing procedure.***
- ***Once the assay has been started, all subsequent steps should be completed without interruption.***
- ***Perform the test on a flat work surface to ensure that reagents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

1. Holding the MedMira Universal Buffer bottle with the drop dispenser tip on a slight angle from vertical, apply **three (3)** drops of MedMira Universal Buffer (through the buffer bottle drop dispenser tip) to the center of each test cartridge to prime the immunoreactive test membrane. Allow the buffer to absorb completely.



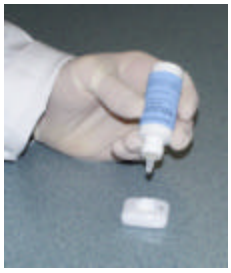
2. Uncap specimen tube(s). Squeeze the bulb of the disposable pipette (provided in the Test Cartridge Mylar pouch) between the thumb and the index finger. Place the tip of the pipette into the specimen. Slowly release the pressure on the bulb to draw the specimen into the channel of the pipette. Apply **one (1)** drop of serum or plasma specimen to the center of the test membrane. If the specimen does not completely absorb into the test membrane within 30 seconds, 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. Prime a new test cartridge as in Step 1 above. Apply **one (1)** drop of the clear specimen supernatant to a new test cartridge. Discard the disposable pipette in a biohazard waste container after use. Ensure that the specimen has absorbed completely into the test membrane before proceeding to the next step.

3. Holding the MedMira Universal Buffer bottle with the drop dispenser tip on a slight angle from vertical, apply **three (3)** drops of MedMira Universal Buffer (through the buffer bottle drop dispenser tip) to the center of the test membrane. Allow the buffer to absorb completely. **Do not touch the buffer bottle drop dispenser tip to the test membrane.**



4. Apply **four (4)** drops of reconstituted MedMira Colorimetric Detection Agent (see above **Section E. Reconstitution of Reagents; part I, MedMira Colorimetric Detection Agent**) to the center of the test cartridge using a disposable pipette (provided in the 4"x4" poly zipper bag of disposable pipettes). Allow the solution to absorb completely. **Do not touch the tip of the disposable pipette to the test membrane.**

5. Holding the MedMira Universal Buffer bottle with the drop dispenser tip on a slight angle from vertical, apply **three (3)** drops of MedMira Universal Buffer (through the buffer bottle drop dispenser tip) to the center of the test membrane. Allow the buffer to absorb completely. **Do not touch the buffer bottle drop dispenser tip to the test membrane.**



6. Read results immediately as indicated in the *Test Results and Interpretation of Results* section below.

7. After recording the test results, dispose of the test cartridges, empty Detection Agent and Test Control vials, both types of disposable pipettes and other testing materials in a biohazard waste container.

8. Follow CDC guidelines to inform the test subject of the test result and its interpretation[12].

QUALITY CONTROL

Built-in Control Features

The *Reveal*™ G2 Rapid HIV-1 Antibody 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 **Test Results and Interpretation of Results** section below).

External Quality Control

One MedMira HIV-1 Human Test Control Package is provided with the test, and is only for use with the *Reveal*™ G2 Rapid HIV-1 Antibody Test. Additional packages are also available as an accessory to the test. The Test Control Package includes two controls, the MedMira Positive Test Control, and the MedMira Negative Test Control. Each test control is reconstituted as indicated in *Section II* of the **Reconstitution of Reagents** section above. **Using individual test cartridges, run one Positive and one Negative Test Control under the following circumstances to monitor proper test performance:**

- **With each new operator prior to performing testing on patient specimens.**
- **When beginning testing with a new lot of test devices.**
- **On each new shipment of tests received.**
- **If the temperature in the storage area for the tests falls outside of the 2-30°C range.**
- **If the temperature in the testing area falls outside of the 2-30°C range.**
- **At periodic intervals as required by the user facility.**

Reconstituted test controls are stable for up to seven (7) days at 2 - 8^0C. Positive and Negative Test Controls are tested using the **Testing Procedure** described above, replacing the specimen in step 1 of the **Testing Procedure**. The Positive Control will produce a Reactive test result indicated by both the red dot in the test zone and a vertical red Control Line upon completion of the test procedure. The expected test result using the Positive Control may be less intense than test results obtained using clinical specimens. In contrast, a Non-Reactive test result is obtained with the Negative Test Control, due to the absence of the HIV-1 antibody, and is indicated by the presence of only the vertical red Control Line on the test membrane.

It is the responsibility of each laboratory using the *Reveal*™ G2 Rapid HIV-1 Antibody Test to establish an adequate quality assurance program to ensure the proper performance of the device under its conditions of use. Contact MedMira's Sales and Marketing Department if the Positive and/or Negative Test Controls do not produce the expected results.

TEST RESULTS AND INTERPRETATION OF RESULTS

Non-Reactive

The diagram to the right is an example of a Non-Reactive test result. The presence of a vertical red Control Line under the **C** and the absence of a red dot next to the **T** on the test membrane indicate that anti-HIV-1 antibodies **were not detected.** The test result is interpreted as **NEGATIVE for HIV-1 antibodies**. A uniform, faint pinkish background may be visible on the test membrane.

Reactive

The diagrams to the right are examples of a Reactive test result. The presence of both a vertical red Control Line under the **C** and a red dot next to the **T** on the test membrane, regardless of intensity, indicate that anti-HIV-1 antibodies **have been detected** in the specimen.

Invalid

The diagrams to the right are examples of an Invalid test result. The absence of the vertical red Control Line, or 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**. **An Invalid test result cannot be interpreted**. If an Invalid test result is obtained, the **Testing Procedure** should be repeated using a new test cartridge and specimen.

LIMITATIONS OF THE TEST

1. The *Reveal*™ G2 Rapid HIV-1 Antibody Test must be used in accordance with this package insert to ensure accurate results.
2. The FDA has approved the *Reveal*™ G2 Rapid HIV-1 Antibody Test for serum or plasma specimens only. Use of other types of specimens may not yield accurate results.
3. Test results are to be read and interpreted **immediately** following the final washing step with Universal Buffer. A delay in reading test results may yield inaccurate results.
4. Specimens that do not pass through the membrane within thirty (30) seconds after centrifugation (see **Testing Procedure, step 2)** are unsuitable for testing with the *Reveal*™ G2 Rapid HIV-1 Antibody Test.
5. Lipemic samples or specimens contaminated with bacteria may not pass through the membrane within thirty (30) seconds, and therefore may be unsuitable for testing with the *Reveal*™ G2 Rapid HIV-1 Antibody Test.
6. Limited studies were conducted to determine the potential effect of interfering substances and unrelated medical conditions on the performance of the *Reveal*™ G2 Rapid HIV-1 Antibody Test.
7. The specificity of the *Reveal*™ G2 Rapid HIV-1 Antibody Test for serum specimens in low-risk populations has not been evaluated.
8. Limited studies were conducted to determine the performance of the *Reveal*™ G2 Rapid HIV-1 Antibody Test on fresh serum and plasma specimens.
9. A Reactive test result using the *Reveal*™ G2 Rapid HIV-1 Antibody Test suggests the presence of anti-HIV-1 antibodies in the specimen. The *Reveal*™ G2 Rapid HIV-1 Antibody Test is intended to be used as an aid in the diagnosis of infection with HIV-1. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically. Results of the *Reveal*™ G2 Rapid HIV-1 Antibody Test should not be used in isolation, but in conjunction with the clinical status, history, and risk factors of the individual being tested.
10. The intensity of the red dot (Reactive test result) does not necessarily correlate with the antibody titre of the specimen.
11. A Non-Reactive test result with the *Reveal*™ G2 Rapid HIV-1 Antibody Test indicates the absence of detectable antibodies to HIV in the specimen. However, a Non-Reactive test result does not exclude the possibility of exposure to, or infection with HIV. Following a recent exposure to HIV, it may take several months for the antibody response to reach detectable levels, during which time testing for antibodies to HIV will not be indicative of true infection status. A comprehensive risk history and clinical judgement should be considered before concluding that an individual is not infected with HIV.

PERFORMANCE CHARACTERISTICS

Note: Test performance was evaluated using the *Reveal*™ Rapid HIV-1 Antibody Test. Additional studies have demonstrated that the *Reveal*™ G2 Rapid HIV-1 Antibody Test performs equivalently.

SENSITIVITY

Serum Specimens

Sensitivity studies were performed using repository HIV-1 antibody positive serum specimens from individuals known to be infected with HIV-1 and freshly collected serum specimens from routine clinical settings in high-risk populations at four clinical sites. Serum specimens were obtained from 483 individuals known to be infected with HIV-1, as well as 2914 serum specimens from previously unscreened individuals from high-risk populations. All 483 serum specimens from known HIV-1 antibody positive individuals that were Repeatedly Reactive using an FDA-licensed HIV-1,2 EIA and were HIV-1 antibody Western blot positive gave Reactive results with the *Reveal*™ Rapid HIV-1 Antibody Test. Of the 2914 previously unscreened serum specimens from individuals from a high-risk population, 124 were Repeatedly Reactive using an FDA-licensed HIV-1,2 EIA, 123 were confirmed positive by Western blot (1 indeterminate result), and 122 were Reactive using the *Reveal*™ Rapid HIV-1 Antibody Test. The results of these studies are shown in Table 1A.

Table 1A. Detection of Anti-HIV-1 Antibodies in Serum Specimens Obtained From Known HIV-1 Antibody Positive Individuals and Routine Clinical Settings in HIV High-Risk Populations

Test Group	Total Samples	*Reveal*™ Reactive	Licensed EIA Repeatedly Reactive	Western Blot Positive
Known HIV-1 Antibody Positive	483	483	483	483
High-Risk Population	2914	122	124*	123
Total	3397	605	607	606

* One specimen was Western blot indeterminate.

The overall sensitivity of the *Reveal*™ Rapid HIV-1 Antibody Test for the detection of anti-HIV-1 antibodies in serum specimens in these studies was calculated to be 605/606 = 99.8% (95% confidence interval; 99.2-100%), combining the number of *Reveal*™ Rapid HIV-1 Antibody Test Reactive results obtained from the study of known HIV-1antibody positive serum specimens with the number of *Reveal*™ Rapid HIV-1 Antibody Test Reactive results obtained from the studies of high-risk populations.

Plasma Specimens

Sensitivity studies were performed using repository HIV-1 antibody positive plasma specimens from individuals known to be infected with HIV-1 and repository plasma specimens from clinically diagnosed AIDS patients. Plasma specimens were obtained from 397 individuals known to be infected with HIV-1, as well as 107 specimens from clinically diagnosed AIDS patients from one clinical site. All 397 plasma specimens were Repeatedly Reactive using an FDA-licensed HIV-1,2 EIA, 395 were Western blot positive (2 Western blot indeterminate) and 395 gave Reactive results with the *Reveal*™ Rapid HIV-1 Antibody Test. Of the 107 specimens from clinically diagnosed AIDS patients, 107 were Repeatedly Reactive using

an FDA-licensed HIV-1,2 EIA, 104 were positive by Western blot (3 Western blot indeterminate) and 103 were Reactive using the *Reveal*™ Rapid HIV-1 Antibody Test. The results of these studies are shown in Table 1B.

1B. Detection of Anti-HIV-1 Antibodies in Plasma Specimens Obtained From Known HIV-1 Antibody Positive Individuals and Clinically Diagnosed AIDS Patients In Routine Clinical Settings

Test Group	Total Samples	*Reveal*™ Reactive	Licensed EIA Repeatedly Reactive	Western Blot Positive
Known HIV-1 Antibody Positive	397	395	397*	395
Clinically Diagnosed AIDS Patients	107	103	107**	104
Total	504	498	504	499

* Two specimens were Western blot indeterminate, ** Three specimens were Western blot indeterminate.

The overall sensitivity of the *Reveal*™ Rapid HIV-1 Antibody Test for the detection of anti-HIV-1 antibodies in plasma specimens in these studies was calculated to be 498/499 = 99.8% (95% confidence interval; 99.0-100%), combining the number of *Reveal*™ Rapid HIV-1 Antibody Test Reactive results obtained from the study of known HIV-1 antibody positive plasma specimens with the number of *Reveal*™ Rapid HIV-1 Antibody Test Reactive results obtained from clinically diagnosed AIDS patients.

Sensitivity of the *Reveal*™ Rapid HIV-1 Antibody Test in the Detection of HIV-1 From Various Geographic Regions

The sensitivity of the *Reveal*™ Rapid HIV-1 Antibody Test for the detection of antibodies to HIV-1 Group M subtypes (A,B,C,D,E,F,G) from various geographic regions was assessed by testing 1026 confirmed HIV-1 antibody positive serum and plasma specimens obtained from various parts of the world. Of these 1026 specimens, 1024 were Reactive using the *Reveal*™ Rapid HIV-1 Antibody Test. Two confirmed HIV-1 antibody positive specimens from Canada were Non-Reactive using the *Reveal*™ Rapid HIV-1 Antibody Test.

Reactivity with Seroconversion Panels

Seven seroconversion panels were tested in comparison to a licensed anti-HIV-1,2 EIA. Each panel consisted of a series of sequential specimens obtained from a single individual undergoing seroconversion. Five of the 7 panels were obtained from a commercial source, while the remaining 2 were from clinical settings. The 7 seroconversion panels consisted of 36 specimens. In this study, the *Reveal*™ Rapid HIV-1 Antibody Test detected seroconversion similarly to the FDA-licensed HIV-1,2 EIA (Table 2).

Table 2. Performance of the *Reveal*™ Rapid HIV-1 Antibody Test with Seroconversion Panels

Specimen Information		*Reveal*™ test	Licensed anti-HIV-1,2 EIA
Panel	Relative Day of Bleed		
AF	1	NR	NR
	3	NR	NR
	8	NR	NR
	10	NR	NR
	16	R	NR
	29	R	RR
	34	R	RR
	36	R	RR
	43	R	RR
D	1	NR	NR
	22	NR	NR
	50	R	NR
	93	R	RR
	100	R	RR
H	1	NR	NR
	8	NR	NR
	13	NR	NR
	20	NR	NR
	27	NR	NR
	29	R	RR
M	1	NR	NR
	23	R	RR

Specimen Information			
Panel	**Relative Day of Bleed**	***Reveal*™ test**	**Licensed anti-HIV-1,2 EIA**
E	1	NR	NR
	8	NR	NR
	22	NR	NR
	36	NR	NR
	43	NR	NR
	50	NR	NR
	64	NR	NR
	85	NR	NR
	92	NR	RR
	127	R	RR
TORONTO PANEL 1	1	NR	RR
	22	R	RR
TORONTO PANEL 6	1	R	NR
	72	R	RR

NR= Non-Reactive; R=Reactive; RR=Repeatedly Reactive

Reactivity with Low Titre HIV-1 Antibody Performance Panel

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 results of the study are shown in Table 3. The *Reveal*™ Rapid HIV-1 Antibody Test was capable of detecting antibodies to HIV-1 similarly to the licensed anti-HIV EIA tests.

Table 3: Comparison of the *Reveal*™ Rapid HIV-1 Antibody Test and Licensed Anti-HIV EIA Tests Using a Low Titre HIV-1 Antibody Performance Panel

Panel Member	***Reveal*™ Test**	**Licensed Anti-HIV EIA Tests**				
		EIA #1	**EIA #2**	**EIA #3**	**EIA #4**	**EIA #5**
1	NR	NR	RR	RR	NR	NR
2	R	NR	RR	RR	RR	NR
3	R	NR	RR	NR	NR	NR
4	R	RR	RR	RR	RR	NR
5	NR	NR	NR	NR	NR	NR
6	R	RR	RR	RR	RR	NR
7	NR	NR	RR	RR	NR	NR
8	NR	NR	RR	NR	RR	NR
9	NR	NR	RR	NR	NR	NR
10	R	RR	RR	RR	RR	RR
11	R	RR	RR	RR	RR	RR
12	NR	NR	RR	NR	NR	NR
13	NR	NR	RR	RR	NR	NR
14	R	RR	RR	RR	RR	RR
15	R	RR	RR	RR	RR	RR

NR=Non-Reactive, R=Reactive, RR=Repeatedly Reactive

Interfering Substances and Unrelated Medical Conditions

The effects of seromarkers associated with unrelated medical conditions was assessed using a panel of specimens testing positive for C-reactive protein (CRP; n=32), antistreptolysin O titre (ASOT; n=8), rheumatoid factor (RF; n=36), infectious mononucleosis (n=14), *Helicobacter pylori* IgG/IgM antibodies (n=16), hepatitis B virus seromarkers (HBsAg, anti-HBc IgG/IgM, and anti-HBs; n=68), hepatitis C virus (anti-HCV antibody / HCV RNA; n=51), hepatitis A virus IgM (anti-HAV; n=7), parvovirus IgG/IgM (n=18), herpes simplex virus IgG (HSV; n=11), cytomegalovirus IgG/IgM (n=9), mycoplasma IgM (n=1), mumps IgG (n=2), measles virus IgM (n=8), rubella IgM (n=5), Epstein-Barr virus (n=6), varicella (n=4), individuals vaccinated against smallpox who possess anti-vaccinia antibodies (n=103). The test panel was comprised of 374 specimens spiked with HIV-1 antibody positive specimens. Of the 374 specimens, 350 contained one of the seromarkers while 24 contained various combinations.

The effect of abnormal blood chemistry on the outcome of the *Reveal ä* Rapid HIV-1 Antibody Test was assessed using a panel comprised of 124 specimens with abnormal blood chemistry that were spiked with HIV-1 antibody positive specimens. Six specimens included in the study contained abnormal levels of alkaline phosphatase (n=1; range of elevated level tested, 299 U/l; reference range, 40-117 U/l), urea (n=2; 1.7-1.8 mmol/l; reference, 7.5-41.6 mmol/l),

creatinine kinase (n=2; 142-1143 U/l; reference, 9-139 U/l), and glucose (n=1; 10 mmol/l; reference, 3.7-6 mmol/l). The remaining 118 specimens contained various combinations of the following analytes: markers related to kidney function: urea (n=38; range of elevated levels tested, 7.5-41.6 mmol/l; reference, 2.5-7.5 mmol/l), creatinine (n=31; 132-1239 µmol/l; reference, 62-115 µmol/l), sodium (n=1; 146 mmol/l; reference, 135-145 mmol/l), potassium (n=11; 5.2-6.4 mmol/l; reference, 3.5-5.3 mmol/l), chloride (n=11; 111-118 mmol/l; reference, 98-110 mmol/l); markers related to liver function: alkaline phosphatase (ALP)(n=34; 121-1248 u/l; reference, 40-117 u/l), alanine amino transferase (ALT)(n=33; 56-634 u/l; reference, 10-55 u/l), gamma glutamyl transferase (GGT)(n=24; 51-940.5 u/l; reference, 0-51 u/l), total protein (n=1; 83 g/l; reference, 63-80 g/l), aspartate aminotransferase (AST)(n=25; 50-1764 u/l; reference, 15-50 u/l), lactate dehydrogenase (LD)(n=17; 211-676 u/l; reference, 15-50 u/l), total bilirubin (n=17; 28-343 µmol/l; reference, 4-24 µmol/l); markers related to lipid profile: cholesterol (n=25; 5.25-9.56 mmol/l; reference, 4-5.2 mmol/l), triglyceride (n=16; 2.02-6.38 mmol/l; reference, 0.4-1.9 mmol/l), HDL cholesterol (n=5; 2.02-2.41 mmol/l; reference, 0.9-2.0 mmol/l), LDL cholesterol (n=14; 3.5-6.7 mmol/l; reference, 1.6-3.4 mmol/l), CHL-LDL ratio (n=22; 4.03-7.4; reference, 0-4), plus others including: glucose (n=32; 3.4-22.9; reference, 3.7-6 mmol/l), amylase (n=4; 29.2-192 U/l; reference, 18-98 U/l) uric acid (n=9; 386-626 µmol/l; reference, 180-440µmol/l), creatinine kinase (CK)(n=12; 142-11344 U/l; reference, 9-139 U/l).

The effect of anticoagulants, EDTA (n=73), heparin (n=89), and sodium citrate (n=20), was also determined.

The results of the studies indicated that none of the above conditions interfered with the sensitivity of the *Reveal*ä Rapid HIV-1 Antibody Test.

SPECIFICITY

Serum Specimens

Specificity studies were performed using repository serum specimens obtained from 850 previously screened HIV-1 antibody negative individuals from a high-risk population and 2914 freshly collected serum specimens from previously unscreened individuals from high-risk populations. Specimens were collected from three clinical sites. Of the 850 repository HIV-1 antibody negative serum specimens, 845 gave Non-Reactive results with the *Reveal*™ Rapid HIV-1 Antibody Test. Of the 2914 freshly collected serum specimens, 2763 gave Non-Reactive results using the *Reveal*™ Rapid HIV-1 Antibody Test. Five of the specimens were found to be Western blot indeterminate. The results of these studies are shown in Table 4A.

Table 4A. Performance of the *Reveal*™ Rapid HIV-1 Antibody Test on Serum Specimens Presumed to be Negative for Antibodies to HIV-1

Test Group	Total Samples	*Reveal*™ Non-Reactive	Licensed EIA Non-Reactive	True Negative*
Known HIV-1 Antibody Negative	850	845	850	850
High-Risk Population	2914	2763	2789	2789
Total	3764	3608	3639	3639

* True Negative status was based on negative or indeterminate test results using a licensed Western blot.

The overall specificity of the *Reveal*™ Rapid HIV-1 Antibody Test for serum specimens in these studies was calculated to be 3608/3639 = 99.1% (95% Confidence Interval; 98.8-99.4%), combining the number of *Reveal*™ Rapid HIV-1 Antibody Test Non-Reactive results obtained from the study of previously screened HIV-1 antibody negative serum specimens with the number of *Reveal*™ Rapid HIV-1 Antibody Test Non-Reactive results obtained from the studies of high-risk populations.

Plasma Specimens

Specificity studies were performed using plasma specimens that had been frozen once, obtained from 1000 previously screened HIV-1antibody negative individuals, and 2011 freshly collected plasma specimens from previously unscreened individuals from low risk-populations. All plasma specimens were collected from the same clinical site. Of the 1000 pre-screened HIV-1 antibody negative plasma specimens, 992 gave Non-Reactive results with the *Reveal*™ Rapid HIV-1 Antibody Test. Of the 2011 freshly collected HIV-1 antibody negative plasma specimens, 1978 gave Non-Reactive results using the *Reveal*™ Rapid HIV-1 Antibody Test. Four of the specimens were found to be Immunofluorescence Assay (IFA) indeterminate. The results of these studies are shown in Table 4B.

Table 4B. Performance of the *Reveal*™ Rapid HIV-1 Antibody Test on Plasma Specimens Presumed to be Negative for Antibodies to HIV-1

Test Group	Total Samples	*Reveal*™ Non-Reactive	Licensed EIA Non-Reactive	True Negative*
Known HIV-1 Antibody Negative	1000	992	1000	1000
Low-Risk Population	2011	1978	2011	2011
Total	3011	2970	3011	3011

* True Negative status was based on negative or indeterminate test results using a licensed Western blot or IFA.

The overall specificity of the *Reveal*™ Rapid HIV-1 Antibody Test for plasma specimens in these studies was calculated to be 2970/3011 = 98.6% (95% Confidence Interval; 98.4-98.8%), combining the number of *Reveal*™ Rapid HIV-1 Antibody Test Non-Reactive results obtained from the study of previously screened HIV-1 antibody negative plasma specimens with the number of *Reveal*™ Non-Reactive results obtained from the studies of low-risk populations.

Interfering Substances and Unrelated Medical Conditions

The effect of seromarkers associated with unrelated medical conditions on the specificity of the *Reveal*ä Rapid HIV-1 Antibody Test was assessed using a panel of specimens. The seromarkers studied were; C-reactive protein (CRP; n=41), antistreptolysin O titre (ASOT; n=19), rheumatoid factor (RF; n=33), infectious mononucleosis (n=17), *Helicobacter pylori*

IgG/IgM antibodies (n=8), hepatitis B virus seromarkers (HBsAg, anti-HBc IgG/IgM, and anti-HBs; n=68), hepatitis C virus (anti-HCV antibody / HCV RNA; n=48), hepatitis A virus IgM (anti-HAV; n=5), parvovirus IgG/IgM (n=20), herpes simplex virus IgG (HSV; n=13), cytomegalovirus IgG/IgM (n=9), mycoplasma IgM (n=11), mumps IgG (n=1), EBV (n=1), human T-Lymphotrophic virus (n=10), measles virus IgM (n=13), rubella IgM (n=13), syphilis reagin (RPR/TPPA; n=16), varicella (n=11), individuals vaccinated against smallpox who possess anti-vaccinia antibodies (n=103). The test panel was comprised of 447 HIV-1 antibody negative specimens. Of the 447 specimens, 422 contained one of the seromarkers while 25 contained various combinations.

The effect of abnormal blood chemistry on the outcome of the *Reveal*ä Rapid HIV-1 Antibody Test was assessed using a panel comprised of 105 HIV-1 antibody negative specimens. Six specimens included in the study contained abnormal levels of uric acid (n=1; range of elevated level tested, 532 µmol/l; reference range, 180-440 µmol/l) glucose (n=1; 7.3, reference, 3.7-6 mmol/l), total bilirubin (n=1; 261.9 µmol/l; reference, 4-24 µmol/l), amalyase (n=1; 2231U/l; reference, 18-98 U/l), creatinine kinase (n=1; 2598 U/l; reference, 9-139U/l), gamma glutamyl transferase (n=1; 1212 U/l; reference, 61-1037U/l). The remaining 99 contained various combinations of the following analytes: markers related to kidney function: urea (n=36; range of elevated levels tested, 7.7-46.1 mmol/l; reference, 2.5-7.5 mmol/l), creatinine (n=38; 121-1214 µmol/l; reference, 62-115 µmol/l), sodium (n=6; 146-152 mmol/l; reference, 135-145 mmol/l), potassium (n=11; 5.3-6.5 mmol/l; reference, 3.5-5.3 mmol/l), chloride (n=6; 111-125 mmol/l; reference, 98-110 mmol/l); markers related to liver function: alkaline phosphatase (ALP)(n=28; 123-1694 u/l; reference, 40-117 u/l), alanine amino transferase (ALT)(n=33; 57-2296 u/l; reference, 10-55 u/l), gamma glutamyl transferase (GGT)(n=21; 61-1037 U/l; reference, 0-51 u/l), total protein (n=1; 125 g/l; reference, 63-80 g/l), aspartate aminotransferase (AST)(n=22; 51-1764 u/l; reference, 15-50 u/l), lactate dehydrogenase (LD)(n=15; 229.5-733 u/l; reference, 15-50 u/l), total bilirubin (n=20; 27-334 µmol/l; reference, 4-24 µmol/l); marker related to lipid profile: cholesterol (n=27; 5.3-32.5 mmol/l; reference, 4-5.2 mmol/l), triglyceride (n=27; 1.91-51.65 mmol/l; reference, 0.4-1.9 mmol/l), HDL cholesterol (n=1; 2.13 mmol/l; reference, 0.9-2.0 mmol/l), LDL cholesterol (n=10; 3..6-27.1 mmol/l; reference, 1.6-3.4 mmol/l), CHL-LDL ratio (n=19; 4.24-10.18; reference, 0-4), plus others including: glucose (n=22; 6.2-15.7; reference, 3.7-6 mmol/l), amylase (n=3; 134-2231 U/l; reference, 18-98 U/l) uric acid (n=6; 252-940 µmol/l; reference, 180-440µmol/l), creatinine kinase (CK)(n=4; 239-2598 U/l; reference, 9-139 U/l).

The effect of anticoagulants; EDTA (n=79), heparin (n=20), and sodium citrate (n=26), on the *Reveal*ä Rapid HIV-1 Antibody Test was also determined.

The results of the studies indicated that none of the above conditions interfered with the specificity of the *Reveal*ä Rapid HIV-1 Antibody Test.

REPRODUCIBILITY

The reproducibility of the *Reveal*™ Rapid HIV-1 Antibody Test was studied at three sites using three lots of the device on three different days by three operators per site. Coded panels of 15 samples were used in triplicate for this study. Each panel consisted of strongly and weakly Reactive HIV-1 antibody serum/plasma samples, as well as HIV-1 antibody negative specimens. In addition, three lots of MedMira Positive and Negative Test Controls were included in the panel. A total of 810 tests were performed (270 per site) with a total of 54 tests performed per panel member. The overall reproducibility of the *Reveal*™ Rapid HIV-1 Antibody Test was found to be 810/810 = 100%.

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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