Procedure Name

CLSI Procedure for Reveal® G4 Rapid HIV-1 Antibody Test

Purpose

The Reveal G4 Rapid HIV-1 Antibody Test (Reveal G4) is a single use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in human whole blood (venipuncture and fingerstick), serum, and plasma. Reveal G4 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 Reveal G4 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.**
- **Reveal G4 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.**
- **Reveal G4 is not approved for use to screen donors of blood, plasma, cells or tissues.**

BACKGROUND

Infection with 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.[1] 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, through transfusion, or from an infected mother during the birthing process or breastfeeding are the major modes of HIV transmission.[2]

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.[3, 4] 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.[5]

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.[5]

Rapid, less complex HIV testing could improve the delivery of medical care and HIV prevention services with substantial time and cost savings.[5, 6] 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.[7] 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.[6,7] Reveal G4 is a rapid, flow-through diagnostic immunoassay developed to utilize the performance characteristics of a conventional diagnostic immunoassay while simplifying the test procedure to eliminate the requirement for expensive equipment and highly trained personnel and decrease turnaround time.

BIOLOGICAL PRINCIPLES OF THE TEST

Reveal G4 is a manually performed, visually interpreted, rapid vertical flow immunoassay.

Reveal G4 is comprised of a single-use, leak-proof plastic 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 whole blood (venipuncture and fingerstick), serum, and 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, captured anti-HIV-1 antibodies are visualized through a reaction with the InstantGold™ cap, a plastic cap housing a filter medium impregnated with a proprietary protein A-colloidal gold conjugate which reacts to form color in the test and control regions so that the test result can be visualized. Universal Buffer, a solution composed of Tris-buffered saline, lysing agents, synthetic polymers and anti-microbial agents (Preservative: 0.05% Proclin 950), is used in the test procedure.

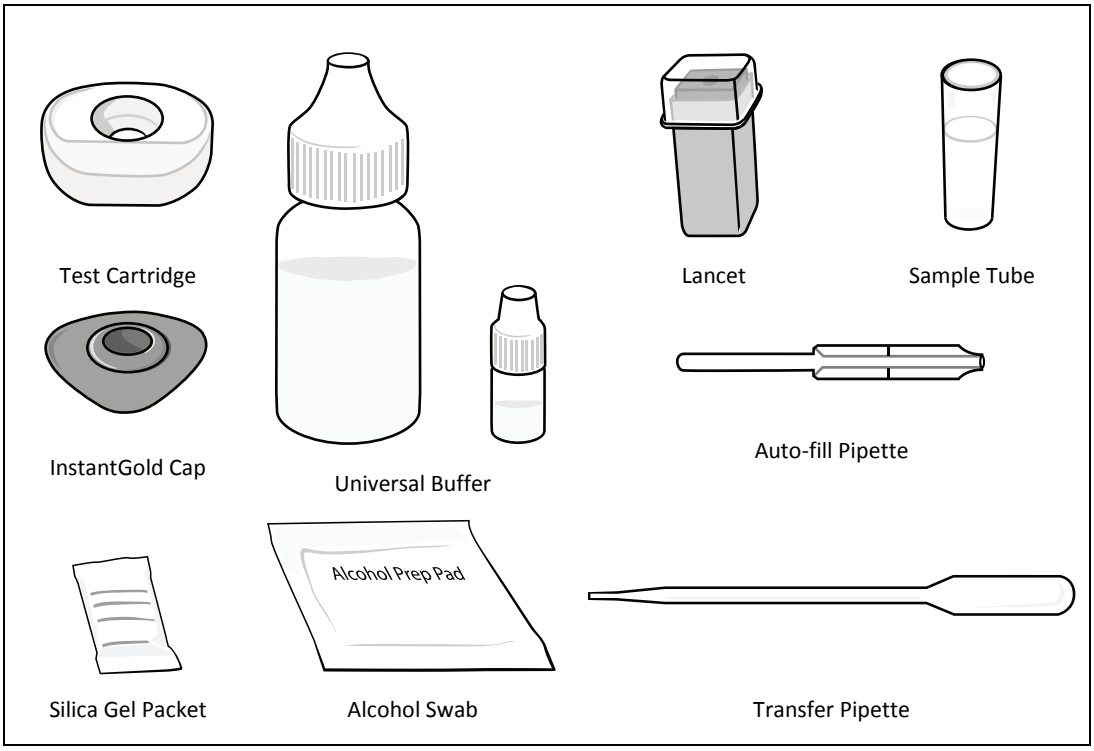
A Reactive test result occurs only when the protein A portion of the conjugate binds to the captured antibodies, producing a distinctive red dot in the test (T) zone and a vertical red Control Line in the control (C) zone of the test membrane upon completion of the test procedure. In contrast, a Non-Reactive 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, or is incomplete, 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 completion of the test procedure. Precision pipetting or specialized equipment are not required to perform Reveal G4.

MATERIALS PROVIDED

Reveal G4 POC **Cat. No. 815311007583** *For Fingerstick Whole Blood*	**Reveal G4 LAB+** **Cat. No. 815311007576** *For Venipuncture Whole Blood/Serum/Plasma*	**Reveal G4 LAB S/P** **Cat. No. 815311000591** *For Serum/Plasma*
20 Mylar pouches each containing: 1 test cartridge 1 InstantGold cap 1 silica gel packet 1 auto-fill pipette 1 sample tube 1 vial Universal Buffer 1 lancet (sterile) 1 alcohol swab 1 test tray 1 package insert 20 Subject Information Brochures 1 Customer Letter	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 Subject Information Brochures 1 Customer Letter	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 50 Subject Information Brochures 1 Customer Letter

Test Components



MATERIALS REQUIRED AND AVAILABLE AS AN ACCESSORY

HIV-1 Antibody Test Controls, Cat. No. 815311007590: Each box contains 1 Mylar pouch with 1 HIV-1 Positive Test Control, 1 HIV-1 Negative Test Control, and 1 silica gel packet, 10 transfer pipettes, 1 vial Reconstitution Buffer and 1 package insert.

ADDITIONAL COMPONENTS AVAILABLE

Universal Buffer, Cat. No. 815311007606: Additional bottles of Universal Buffer may be purchased, subject to availability.

MATERIALS REQUIRED BUT NOT PROVIDED

- Personal protective equipment such as disposable gloves, laboratory coat, and eye protection
- Absorbent cotton for fingerstick or venipuncture wound closure
- Permanent marking pen
- Appropriate biohazard waste containers and disinfectants

SPECIMEN HANDLING/COLLECTION AND USE

Provide the *Subject Information Brochure* to the test subject prior to specimen collection.

Serum and Plasma (Cat. No. 815311007576 or Cat. No. 815311000591)

1. Plasma obtained using EDTA, heparin, or sodium citrate as anticoagulant is suitable for testing.
2. Fresh serum and plasma specimens may be tested immediately upon receipt or stored at 2-8°C (35-45°F) for up to five (5) days prior to testing. Serum and plasma specimens should be stored at -20°C (-4°F) or below if storage is necessary for more than five (5) days.
3. Particulate matter can block the test membrane or cause high background color making interpretation of results difficult. Cloudy or viscous specimens should not be used for testing.
4. If serum or plasma specimens are to be shipped, dispatch by the fastest means available. Package specimens in compliance with statutory regulations governing transportation of dangerous goods.
5. 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°C (95°F), specimens should be shipped at 2-8°C (35-45°F).
6. For serum or plasma that has been previously frozen:
    a. Thaw completely at room temperature (15-27°C, 60-80°F) 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, 60-80°F) at 3361 g (radius of rotor 8.35 cm = 6000 rpm) for at least five (5) minutes and use only the clear supernatant for testing.
7. Avoid multiple freeze-thaw cycles. Serum and plasma specimens should not be frozen and thawed more than twice prior to use with Reveal G4.
8. Proceed to GENERAL TEST PREPARATION.

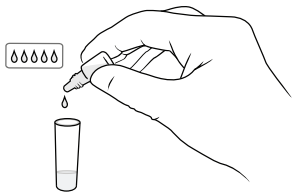
Venipuncture Whole Blood (Cat. No. 815311007576)

1. Use standard venous phlebotomy procedures to collect a whole blood sample in a tube containing K_2EDTA anticoagulant. If specimens are not tested at the time of collection, they may be stored at 2-8°C (35-45°F) for up to five (5) days prior to testing. Prior to testing, mix the blood by gentle inversion several times.*
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 color.
5. Proceed to GENERAL TEST PREPARATION.

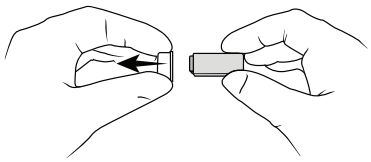
*If storage is necessary for over five (5) days, plasma should be separated from the whole blood specimen and the plasma should be stored at -20°C (-4°F) or below.

Fingerstick Whole Blood (Cat. No. 815311007583)

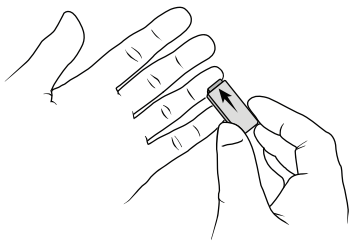
1. Place the sample tube into the hole of the test tray.
2. Add five (5) drops from the vial of Universal Buffer to the sample tube.



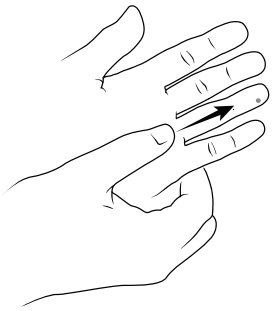
3. Using an alcohol swab, clean the index finger. Allow the finger to dry thoroughly.
4. Remove the protective cap from the sterile lancet provided with the test. Do not use lancet if damaged.



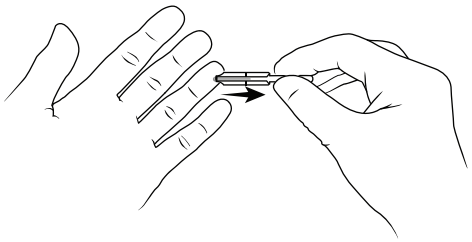
5. Firmly press the lancet against the puncture site to activate the device and puncture the skin.



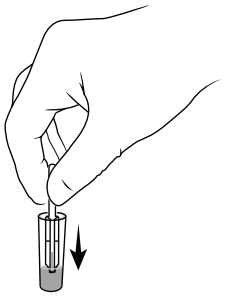
6. Point the lanced finger downward, apply gentle pressure massaging the lanced finger vertically from the base of the finger towards the lanced fingertip to form a drop of blood. Avoid squeezing the fingertip to make it bleed.



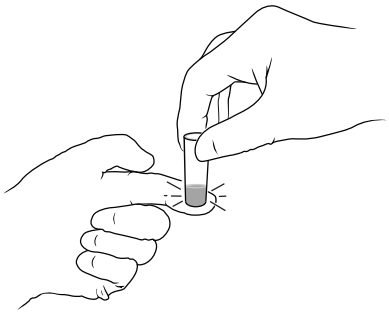
7. Use the auto-fill pipette provided to collect a drop of blood from the fingerstick site. To do this, touch the tip of the pipette to the blood sample in a horizontal position. The blood sample will be automatically drawn to the black fill line and stop. Do not squeeze the pipette bulb during filling.



8. Place the tip of the auto-fill pipette into the Universal Buffer in the sample tube (prepared in Step 2). Squeeze the bulb to empty the blood sample into the tube. Discard the auto-fill pipette.



9. Hold the sample tube and gently tap the side of the tube near the bottom until the mixture becomes a clear reddish color.



10. Proceed to GENERAL TEST PREPARATION

GENERAL TEST PREPARATION

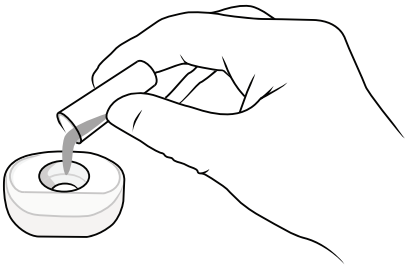
1. Allow all test components and specimens to equilibrate to room temperature (15-27°C, 60-80°F) for 30-60 minutes prior to opening the container or Mylar pouch.
2. Using the notched corners, tear open the required number of Mylar pouches.
    a. Ensure that a silica gel packet is present in each pouch. If the silica gel packet is not present, discard that pouch and all of its contents and open a new pouch.
    b. 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 that pouch and all of its contents and open a new pouch.
    c. Inspect each InstantGold cap to ensure that the blue plastic casing is snapped securely around the rose-colored filter medium. If this is not the case, discard that pouch and all of its contents and open a new pouch.
3. 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.
4. Proceed to TEST PROCEDURE.

TEST PROCEDURE

- **All solutions must be completely absorbed into the test membrane before proceeding to the next step in the test 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.**
- **Hold the Universal Buffer bottle at a slight angle from vertical when dispensing drops of buffer.**
- **Do not let the buffer bottle drop tip touch the immunoreactive membrane.**
- **Read the test results immediately. Failure to do so may result in inaccurate test results.**
- **Follow CDC guidelines to inform the test subject of the test result and its interpretation.** [8]
- **After recording test results, dispose of test materials in biohazard waste container.**

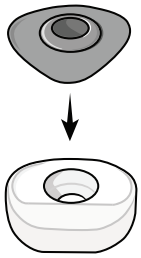
WHOLE BLOOD PROCEDURE - (Cat. No. 815311007583 or 815311007576)

1



Pour the entire contents of the sample tube into the center of the test cartridge. Allow the specimen to absorb completely.

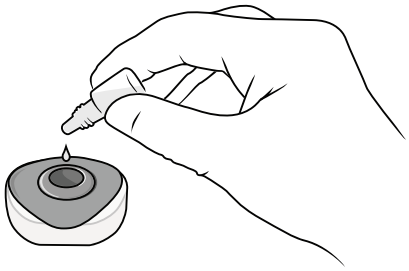
2



Place the InstantGold cap on the test cartridge.

Select the catalog number that corresponds to the test format being used and proceed to the next step.

3 **Cat. No.815311007583 (POC)**



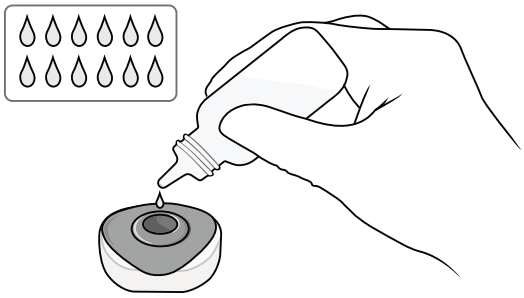
Dispense the remaining buffer from the vial of Universal Buffer onto the InstantGold cap and allow the solution to absorb completely.

Remove the InstantGold cap and wait for the solution to absorb completely.

Read test results immediately.

OR

3 **Cat. No.815311007576 (LAB +)**



Dispense twelve (12) drops of Universal Buffer onto the InstantGold cap, wait for the solution to absorb completely.

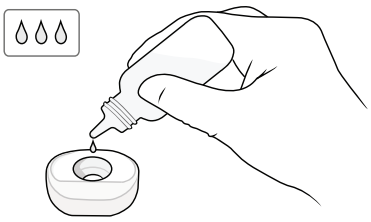
Remove the InstantGold cap and wait for the solution to absorb completely.

Add three (3) drops of Universal Buffer to clarify results.

Read test results immediately.

SERUM/PLASMA PROCEDURE - (Cat. No. 815311007576 or 815311000591)

1



Apply three (3) drops of Universal Buffer to the center of the test cartridge.

Allow the buffer to absorb completely.

2

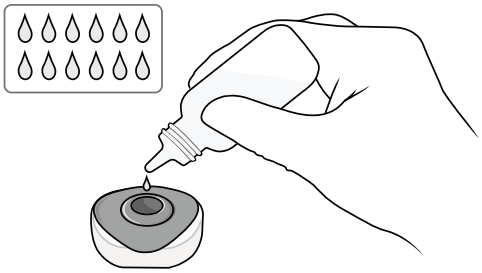
Apply one (1) drop of serum or plasma specimen to the center of the test cartridge. Allow the specimen to absorb completely.*

Apply three (3) drops of Universal Buffer to the center of the test cartridge. Allow the buffer to absorb completely.

Place the InstantGold cap on the test cartridge.

*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, 60-80°F) at 3361g (radius of rotor 8.35cm=6000 rpm) for at least five (5) minutes. Test the clear supernatant using a new test cartridge. If slow absorption persists after centrifugation, the specimen may not be suitable for use.

3



Dispense twelve (12) drops of Universal Buffer onto the InstantGold cap, wait for the solution to absorb completely.

Remove the InstantGold cap and wait for the solution to absorb completely.

Optional – Add three (3) drops of Universal Buffer to clarify results.

Read test results immediately.

QUALITY CONTROL

Built-in Control Features

Reveal G4 includes a built-in procedural and reagent Control Line that demonstrates the validity of the test 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

HIV-1 Antibody Test Controls (Cat. No. 815311007590) are available separately for use only with Reveal G4. The test controls are used to monitor proper test performance. The Positive Test Control and the Negative Test Control are to be run using separate test cartridges. The Positive Test Control will produce

a Reactive test result indicated by both the red dot in the test zone beside the T on the test and a vertical red Control Line under the C on the test upon completion of the test procedure. The expected test result using the Positive Test 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 and is indicated by the presence of only the vertical red Control Line under the C on the test. Use of test controls manufactured by other any other source may not produce the required results, and therefore would not meet the requirements for an adequate quality assurance program for Reveal G4.

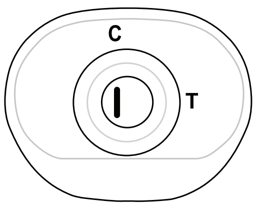
Run the HIV-1 Antibody Test Controls under the following circumstances:

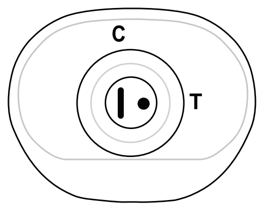
- **With each new operator prior to performing testing on patient specimens.**
- **When beginning testing with a new lot of test devices.**
- **On each new shipment of tests received.**
- **If the temperature in the storage area for the tests falls outside of the 2-30°C (35-85°F) range.**
- **If the temperature in the testing area falls outside of the 2-30°C (35-85°F) range.**
- **At periodic intervals as required by the user facility.**

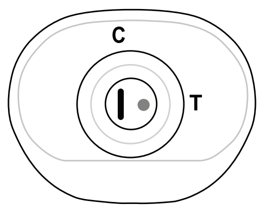
Refer to the HIV-1 Antibody Test Controls package insert for additional information on the use of these reagents. It is the responsibility of each laboratory using Reveal G4 to establish an adequate quality assurance program to ensure the proper performance of the device under its conditions of use. Contact MedMira's Customer Service Department if the HIV-1 Antibody Test Controls do not produce the expected results.

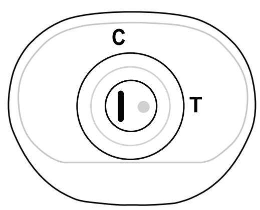
TEST RESULTS AND INTERPRETATION OF RESULTS

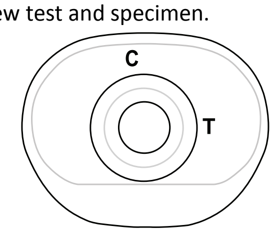
NON-REACTIVE Probable Non-Exposure to HIV	REACTIVE Probable Exposure to HIV	INVALID
The diagram below is an example of a Non-Reactive test result. The presence of a vertical red Control Line under the C and the absence of a red dot next to the T on the test indicate that anti-HIV-1 antibodies were not detected. The test result is interpreted as NEGATIVE for HIV-1 antibodies. A uniform, faint pinkish background may be visible on the test membrane.	The diagrams below 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 indicate that anti-HIV-1 antibodies have been detected in the specimen. The intensity of the line and the dot may vary. Any visible dot next to the T must be considered to be a Reactive result, regardless of how faint the dot appears.	The diagrams below 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, even if there is a red dot beside the T, indicates that there has been a problem, either with the test device or the specimen, during the Test Procedure. An Invalid test result cannot be interpreted. If an Invalid test result is obtained, the Test Procedure should be repeated using a new test and specimen.

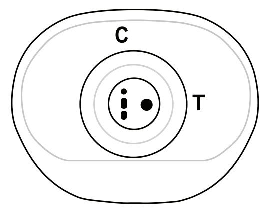


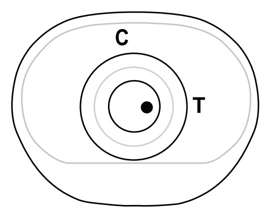


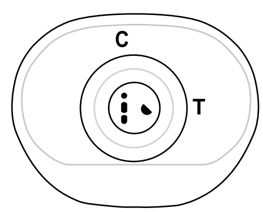












Limitations of the Test

1. Reveal G4 must be used in accordance with this package insert to ensure accurate results.
2. The FDA has approved Reveal G4 for use with fingerstick whole blood, venipuncture whole blood, serum, and 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 completion of the Test Procedure. A delay in reading test results may yield inaccurate results.
4. Specimens (including hemolyzed specimens) that, after centrifugation, do not pass through the membrane within thirty (30) seconds, (see SERUM/PLASMA TEST PROCEDURE, step 2) are unsuitable for testing with Reveal G4.
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 Reveal G4.
6. Limited studies were conducted to determine the potential effect of interfering substances and unrelated medical conditions on the performance of Reveal G4.
7. The specificity of Reveal G4 for serum specimens in low-risk populations has not been evaluated.
8. Limited studies were conducted to determine the performance of Reveal G4 on fresh serum and plasma specimens.
9. A Reactive test result using Reveal G4 suggests the presence of anti-HIV-1 antibodies in the specimen. Reveal G4 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 Reveal G4 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 titer of the specimen.
11. A person who has antibodies to HIV-1 is presumed to be infected with the virus, however, a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counselling, medical evaluation, and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.
12. A Non-Reactive test result with Reveal G4 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 evaluation should be considered before concluding that an individual is not infected with HIV.

WARNINGS

IVD For *In Vitro* Diagnostic Use

- Read the package insert completely and carefully prior to use of Reveal G4. If the directions are not followed exactly, inaccurate test results may occur.
- Before performing Reveal G4, operators must be familiar with *Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health Care Settings*.[8]
- The United States Food and Drug Administration has approved this test for use with human whole blood (venipuncture and fingerstick), serum, and plasma specimens only. Use of this test with specimens other than those specifically approved for use with Reveal G4 may result in inaccurate test results.
- Perform Reveal G4 at room temperature (15-27°C, 60-80°F).
- Perform Reveal G4 on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.

PRECAUTIONS

Safety Precautions

- Handle all specimens, HIV-1 Antibody Test Controls, and 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 containment level 2 practices as described in *Canadian Laboratory Biosafety Standards & Guidelines*, the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*, the WHO *Biosafety Manual*, or the CDC Universal Precautions.[9,10,11,12]
- Do not smoke, eat, or drink in areas where specimens or test reagents are handled. Do not pipette by mouth.
- Wear disposable gloves, laboratory coat and eye protection throughout the test procedure. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
- Dispose of all test specimens and materials used in the test in a biohazard waste container. The recommended method of disposal is autoclaving for a minimum of 1 hour at 121°C or by incineration. Add an equal volume of freshly prepared 5% sodium hypochlorite solution (household bleach) to liquid waste and allow it to soak for at least 1 hour for disinfection. Do not autoclave solutions that contain bleach.
- Wipe spills promptly with a 1% sodium hypochlorite solution (five-fold v/v dilution of household bleach, prepared fresh daily) or other appropriate disinfectant.[13] Contaminated materials should be disposed of in a biohazard waste container.
- For additional information on biosafety, refer to *Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health Care Settings*[8] and *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis*.[13]

Handling Precautions

- Use test components only once, excluding bottles of Universal Buffer in LAB+ and LAB S/P products, and dispose of properly (see Safety Precautions). Do not reuse these components.
- Do not use Reveal G4 or any of its components beyond the expiration date. The expiration date can be found on the test pouch or box. Always check the expiration date prior to testing. If Reveal G4 is expired, discard and obtain a new Reveal G4 test.
- Do not interchange InstantGold caps, Universal Buffer or test devices from different lots.
- Exercise care in handling test components and do not touch the immunoreactive test membrane to prevent contamination.
- Adequate lighting is required to read the test result.

STORAGE INSTRUCTIONS

- Store Reveal G4 tests in a dry area at 2-30°C (35-85°F).
- Keep the Mylar pouches sealed until immediately prior to use. Ensure that the Mylar pouch is intact prior to opening. If the pouch is not intact, discard and obtain a new pouch.
- If tests and reagents are stored at refrigerated temperatures, allow all test components and specimens to equilibrate to room temperature (15-27°C, 60-80°F) for 30-60 minutes prior to opening the packages.

References

1. McCutchan, FE. *Global Epidemiology of HIV*, J. Med. Virol. 2006, 78:S7-S12.
2. Schreibman, T., Friedland, G. *Human Immunodeficiency Virus Infection Prevention: Strategies for Clinicians*, Clin. Infect. Dis. 2003, 36:1171-6.
3. CDC. *Revised Guidelines for HIV Counseling, Testing and Referral*. MMWR Recommendations and Reports. 2001, 50(RR-19).
4. *Guidelines for Using HIV Testing Technologies in Surveillance, Selection, Evaluation and Implementation – 2009 Update*, UNAIDS/WHO Working Group on Global HIV/AIDS/STI Surveillance, 2009.
5. Branson, B.M., *Point-of-Care Rapid Tests for HIV Antibodies*, J. Lab. Med. 2003, 27:288-295.
6. Schito, M.L. et al., *Challenges for Rapid Molecular HIV Diagnostics*, J. Infect. Dis. 2010, 201:51.
7. CDC. *Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings*. MMWR Recommendations and Reports. 1988. 37(24):377-388.
8. CDC. *Rapid HIV Test Distribution – United States*, 2003-2005, 2006, 55:673-676.
9. *Canadian Laboratory Biosafety Standards & Guidelines: 1st Edition*, Public Health Agency of Canada, 2013.
10. *Biosafety in Microbiological and Biomedical Laboratories: 5th Edition*, US Department of Health and Human Services, 2009.
11. *Laboratory Biosafety Manual: Third Edition*, World Health Organization, 2004. Geneva.
12. Siegel, JD et al., 2007 *Guideline for Isolation Precautions: Preventing Transmission of Infections Agents in Healthcare Settings*, 2007. CDC.
13. Whidmer, A.F., Frei, R., "Decontamination, Disinfection, and Sterilization" in *Manual of Clinical Microbiology, 10th Edition*. ASM Press, 2011.

Related Documents

Reveal G4 Rapid HIV-1 Antibody Test Package Insert

Subject Information Brochure

Customer Letter

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