HIV-1/2 Antibody Test Controls

Read this package insert and the Reveal® G4 Rapid HIV-1/2 Antibody Test (Reveal G4) package insert completely before using this product. Instructions must be followed carefully. If directions are not followed exactly, inaccurate test results may occur. Operators must be familiar with the CDC's Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health Care Settings.[1]

INTENDED USE

HIV-1/2 Antibody Test Controls (Test Controls) are external quality control agents intended for use **only** with Reveal G4.

The Test Controls should be used in conjunction with Good Laboratory Practices in laboratories that have established an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met. Run one HIV-1 positive, one HIV-2 positive and one Negative Test Control under the following circumstances:

- By each new operator prior to performing testing on patient specimens
- When beginning testing with a new lot of Reveal G4 tests
- On each new shipment of Reveal G4
- If the temperature of the storage area for Reveal G4 falls outside of the 2-30°C (35-85°F) range
- If the temperature of the testing area where Reveal G4 is being used falls outside of the 2-30°C (35-85°F) range
- At periodic intervals as required by the user facility

SUMMARY AND EXPLANATION OF THE TEST CONTROLS

The Test Controls have been designed for use with Reveal G4 to monitor proper test performance.

The Positive Test Controls have been manufactured to produce a Reactive test result. The Negative Test Control has been manufactured to produce a Non-Reactive test result. The Reconstitution Buffer is used to reconstitute the vials of lyophilized Positive and Negative Test Controls and is a solution composed of Tris-buffered saline, lysing agents, synthetic polymers, and antimicrobial agents (Preservative: 0.05% Proclin 950).

MATERIALS PROVIDED

The Test Controls (Cat. No. 815311007590) are available as an accessory to Reveal G4.

Component	Quantity
Each box contains a Mylar pouch with: 1 HIV-1/2 Antibody Negative Test Control - a vial containing lyophilized human serum/plasma negative for HIV antibodies, hepatitis B surface antigen, and hepatitis C antibodies as confirmed by FDA approved methods, in a buffered solution. Each vial is sufficient to perform five (5) Reveal G4 tests. 1 HIV-1 Antibody Positive Test Control - a vial containing lyophilized, heat-inactivated human serum/plasma positive for HIV-1 antibodies, and negative for hepatitis B surface antigen and hepatitis C antibodies as confirmed by FDA approved methods, in a buffered solution. Each vial is sufficient to perform five (5) Reveal G4 tests. 1 HIV-2 Antibody Positive Test Control - a vial containing lyophilized, heat-inactivated human serum/plasma positive for HIV-2 antibodies, and negative for hepatitis B surface antigen and hepatitis C antibodies as confirmed by FDA approved methods, in a buffered solution. Each vial is sufficient to perform five (5) Reveal G4 tests. 1 silica gel packet	1
Package Insert	1
Reconstitution Buffer	1
Transfer pipettes	15

MATERIALS REQUIRED BUT NOT PROVIDED

- Reveal G4 tests
- Personal protective equipment such as disposable gloves, laboratory coat, and eye protection
- Permanent marking pen
- Appropriate biohazard waste containers and disinfectants.

WARNINGS

IVD **For *in vitro* diagnostic use only.**

- **These test controls are intended for use with Reveal G4 only.**
- **The sale of Reveal G4 and the associated materials is restricted to clinical laboratories.**
- **Read this package insert and the Reveal G4 package insert completely before using this product. Instructions must be followed carefully. If directions are not followed exactly, inaccurate test results may occur.**
- **The Test Controls contain human source material and should be treated as potentially infectious in accordance with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health Care Settings.[1]**
- **To avoid contamination, ensure that the Test Controls are reconstituted one at a time, as indicated in the instructions below. Do not interchange stoppers on the Test Control vials.**

SAFETY RECOMMENDATIONS

- Handle all Test Controls, specimens, and materials contacting specimens as if capable of transmitting infectious agents. It is recommended that all specimens and reagents are handled according to the CDC Universal Precautions.[1,3]

  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 while handling Test Controls. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.

  Wipe spills promptly with a 1% sodium hypochlorite solution (five-fold v/v dilution of household bleach, prepared fresh daily) or other appropriate disinfectant.[2] Contaminated materials should be disposed of in a biohazard waste container.

  Dispose of all test specimens and materials used in the test procedure 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.**

  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.*[1]

HANDLING AND STORAGE INSTRUCTIONS

- Exercise care in handling test components to prevent contamination.
- Store unopened Test Controls in a dry place at 2 - 30°C (35-85°F).
- Keep the Test Controls in the sealed Mylar pouch until use. Ensure that the Mylar pouch is intact and that the expiration date on the outside of the pouch is valid. If the pouch is not intact or is expired, discard and obtain a new pouch.
- Following reconstitution, Test Controls may be used or stored at 2 - 8°C (35-45°F) for up to twenty-one (21) days after reconstitution. Unused Test Controls should be discarded as liquid biohazardous waste.
- Adequate lighting is required to read the test result.

DIRECTIONS FOR USE

A. General Test Preparation

1. Allow the Test Controls and the Reveal G4 tests to equilibrate to room temperature (15-27°C, 60-80°F) for 30-60 minutes prior to opening the container or Mylar pouch.
2. Refer to the Reveal G4 package insert for test preparation instructions.

B. Reconstitution of Test Controls

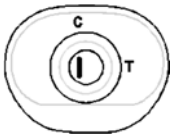
Test Controls should be reconstituted immediately prior to performing the test procedure. One Test Control vial contains sufficient quantity to perform five (5) tests.

1. Using the notched corners, tear open the Test Controls Mylar pouch. Ensure that the HIV-1 Positive Test Control, the HIV-2 positive Test control, the Negative Test Control, and a silica gel packet are present.
2. Carefully remove the rubber stopper from the Negative Test Control vial.
3. Add six (6) drops of Reconstitution Buffer through the drop tip dispenser into the vial.
4. Replace the stopper tightly and gently mix by tapping the bottom of the vial until all of the lyophilized control material has dissolved. **Do not invert the vial to mix, this will result in excess foaming.**
5. The mixed solution should be a clear to light yellow and completely dissolved with no particulate matter visible. If this is not the case, contact MedMira Customer Service for replacements.
6. Repeat Steps 2-5 for each Positive Test Control.
7. Write the dates of reconstitution and expiration (twenty-one (21) days later) on the vials with a permanent marking pen. It is recommended that the stoppers are sealed additionally with Parafilm or a similar material.
8. The Test Controls should be stored at 2-8°C (35-45°F) for up to twenty-one (21) days after reconstitution. After twenty-one (21) days, they should be discarded as biohazardous liquid waste.

C. Testing Procedure

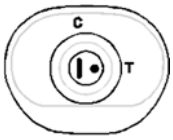
Refer to the Reveal G4 package insert for the test procedure instructions.

EXPECTED RESULTS



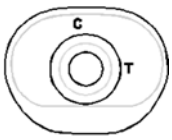
Negative Test Control

The presence of a vertical red line under the **C** and the absence of a red dot next to the **T** on the test membrane indicates there are no anti-HIV antibodies detected in the control material. This is the expected result.



Positive Test Control

The presence of a vertical red line under the **C** with a red dot next to the **T** on the test membrane indicates there are anti-HIV antibodies detected in the control material. This is the expected result.



Invalid Results

If no red line appears under the **C**, even if a dot appears next to the **T**, the result is considered invalid. Also, the presence of a broken line under the **C** indicates that there has been a problem, either with the test device or the control material, during the Test Procedure and the result is invalid.

If an Invalid result occurs when using the Test Controls, the test procedure should be repeated with the appropriate test control and a new Reveal G4 test. If the problem persists, contact MedMira Customer Service.

If the expected result is not achieved, contact MedMira Customer Service.

LIMITATIONS OF THE TEST

1. The Test Controls are for use only with Reveal G4.
2. The results obtained using the Test Controls depend on several factors. Erroneous results can occur from improper storage, improper reconstitution, or handling errors associated with testing procedures.

PRODUCT WARRANTY

MedMira Laboratories Inc. guarantees the quality of this product if stored and used as instructed. If this material is found to be defective, it 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.

LITERATURE CITED

1. CDC. *Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood-borne Pathogens in Health-Care Settings*. MMWR Recommendations and Reports. 1988. 37(24):377-388.
2. Whidmer, A.F.; Frei, R., "Decontamination, Disinfection, and Sterilization" in *Manual of Clinical Microbiology*, 10th Edition. ASM Press, 2011.
3. *Biosafety in Microbiological and Biomedical Laboratories: 5th Edition*, US Department of Health and Human Services, 2009.

Explanation of Symbols

	Temperature Limit		Use by date
	Manufacturer	IVD	For *In Vitro* Diagnostic Use
REF	Catalogue number		Consult instructions for use
LOT	Lot number		

Manufacturer:
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