HIV-1 Antibody Test Kit Controls

Product Number: 80-1071

Read this Package Insert and the INSTI™HIV-1 Antibody Test Package Insert before using this product. Conformance with the test procedure is necessary to ensure accurate results. Before performing the test, all operators must become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health Care Settings[1]

NAME AND INTENDED USE

The INSTI™ HIV-1 Antibody Test Kit Controls are intended to be used **only** with the *INSTI™HIV-1 Antibody Test*.

SUMMARY

INSTI™ HIV-1 Positive and Negative Controls should be used in conjunction with Good Laboratory Procedures. They should be run under the following circumstances:

- for new INSTI™ operator verification prior to performing testing on patient specimens
- when switching to a new lot number of INSTI™ test kits
- whenever a new shipment of kits is received
- when temperature during storage of the kit falls outside of 15°-30°C (59°-86°F)
- when the temperature of the test area falls outside of 15°-30°C (59°-86°F)
- At regular intervals as determined by the user facility.

PRINCIPLES OF THE PROCEDURE

The INSTI™ HIV-1 Antibody Test Kit Controls have been designed for use with the INSTI™ HIV-1 Antibody Test to validate the correct performance of the test procedure in the hands of the operator.

The INSTI™ HIV-1 Antibody Test Kit Positive Control is prepared from inactivated human plasma. It is negative for HBsAg and anti-HCV by U.S. FDA licensed test procedures.

The Positive Control has been designed to produce an easily visible but faint blue color on the INSTI™ test spot and a darker blue color on the control spot.

The INSTI™ HIV-1 Antibody Test Kit Negative Control is prepared from defibrinated human serum which is negative for Anti-HIV-1 and Anti-HIV-2, HBsAg, and Anti-HCV. The Negative Control will produce a blue color on the procedure control spot, but no color on the test spot, for a Non-Reactive INSTI™ test result.

REAGENTS:

POSITIVE CONTROL

10 vials with red caps, each containing 0.4 ml of inactivated human plasma. Each vial is sufficient for 8 INSTI™ tests. The source material has been heat inactivated at 60°C for 60 minutes.

NEGATIVE CONTROL

10 vials with green caps, each containing 0.4 ml of defibrinated human serum. Each vial is sufficient for 8 INSTI™ tests.

Both the Positive and Negative Controls contain 0.1% Sodium Azide as a preservative.

WARNINGS & PRECAUTIONS

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

Safety Precautions:

1. All specimens should be handled as if capable of transmitting infectious agents.
2. Thoroughly wash hands after handling or performing this test.
3. Do not smoke, eat, or drink in areas where specimens or kit reagents are being handled.
4. Wear disposable gloves while handling kit reagents or specimens. Do not pipette by mouth.
5. Avoid contact with skin and eyes. If contact occurs, wash affected areas with water.
6. Avoid forming aerosols.
7. Dispose of all specimens and materials used to perform the test in a biohazard waste container. The preferred method of disposal is sterilization by autoclaving for a minimum of one hour at 121°C. Disposable materials may be incinerated. Liquid waste may be mixed with sodium hypochlorite (bleach) in volumes such that the final mixture contains 1.0% sodium hypochlorite (using a freshly prepared solution containing 10% household bleach). Allow at least 60 minutes for decontamination to be completed. **Do not autoclave solutions that contain bleach**.
8. Spills should be cleaned up and decontaminated in accordance with the user facility's established procedures for handling biohazardous spills.
9. For additional information on bio-safety 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] and "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis"[2].

Handling Precautions:

1. Do not use INSTI™ HIV-1 Antibody Test Kit Controls beyond the expiration date.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Positive or Negative Controls that are visibly turbid and/or contain particulate matter should not be used and should be discarded in accordance with safety precautions.

STORAGE INSTRUCTIONS

1. Store the INSTI™ HIV-1 Antibody Test Kit Controls at 2 - 8°C (35.6 – 46.4°F) for up to 28 days or at ≤-20 °C (-4°F) for up to 1 year.
2. Store in an upright position at all times to prevent leakage.
3. Once the controls are thawed following storage at ≤-20 °C (-4°F), they remain stable for 28 days at 2 - 8°C (35.6 – 46.4°F). Do not re-freeze.

PROCEDURE

Materials Required but not Provided

- Precision pipette capable of delivering 50µl of specimen.
- INSTI™ HIV-1 Antibody Test Package Insert.

Instructions for use

1. Read the INSTI™ HIV-1 Antibody Test Kit Controls Package Insert prior to using the INSTI™ HIV-1 Antibody Test Kit Controls.
2. Remove from storage at 2 - 8°C (35.6 – 46.4°F) or ≤ 20 °C (-4°F) and allow the Controls to reach room temperature before testing with INSTI™. Return Controls to storage at 2-8°C after use.
3. Mix the Controls by swirling before use.
4. Uncap the Positive or Negative Control vial. Using a calibrated 50µl precision pipette and clean unused tip, collect 50µl of the Positive or Negative Control.
5. Transfer the Control sample held in the pipette to the INSTI™ Sample Diluent vial (Solution 1). Recap the vial and mix by inversion.
6. Follow the INSTI™ test procedure as described in the TEST PROCEDURE section of the INSTI™ HIV-1 Antibody Test Kit Package Insert.
7. All Controls should be tested in the same manner as patient samples.
8. The Positive Control and the Negative Control are to be run on separate Membrane Units.

INTERPRETATION OF RESULTS

- Follow the interpretation guidelines provided in the INTERPRETATION OF RESULTS section of the INSTI™ HIV-1 Antibody Test Package Insert.
- **Reactive Result:** Both the control spot and the test spot show blue color development.
- **Non-Reactive Result**: Only the control spot shows blue color development.
- **Invalid Result**: The test is invalid if any of the following occurs:
  -There is no blue color on both the control spot and the test spot
  -There is blue color on the test spot but not on the control spot
  -Uniform tint across the membrane
  -Only blue specks appear on the membrane

LIMITATIONS OF THE PROCEDURE

The INSTI™ HIV-1 Antibody Test Kit Controls are only validated for use with the INSTI™ HIV-1 Antibody Test.

1. The TEST PROCEDURE and INTERPRETATION OF RESULTS sections of the INSTI™ HIV-1 Antibody Test package insert must be adhered to when testing the INSTI™ HIV-1 Antibody Test Kit Controls.
2. Deviations from the procedure outlined in the INSTI™ HIV-1 Antibody Test Package Insert may produce unreliable results.
3. Do not dilute the INSTI™ HIV-1 Antibody Test Kit Controls. The INSTI™ HIV-1 Antibody Test Kit Controls are intended for use in undiluted form.
4. Adverse shipping and storage conditions or use of expired reagents may produce erroneous results.

EXPECTED RESULTS

The Positive Control must be Reactive with INSTI™ and the Negative Control must be Non-Reactive with INSTI™. Controls that produce incorrect or invalid results must be re-tested with INSTI™.

Contact bioLytical Laboratories' Technical Support if the INSTI™ HIV-1 Antibody Test Kit Controls do not produce the expected results.

REFERENCES

1. CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health care settings. *MMWR* 1988; 37(24):377-388

2. CDC Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR* 2001; 50(RR-11):1-42.

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