HIV-1/HIV-2 Test Controls
Product Number: 90-1031, 90-1030

Store at -20°C for up to one year
Store at 2-8°C for up to one year

Use by

Caution
Harmful if swallowed

Manufacturer

Consult Package Insert

Read this Package Insert and the INSTI® HIV-1/HIV-2 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/HIV-2 Test Controls are intended to be used **only** with the *INSTI HIV-1/HIV-2 Antibody Test*.

SUMMARY
INSTI HIV-1/HIV-2 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 2°-30°C (35.6°-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/HIV-2 Test Controls have been designed for use with the INSTI HIV-1/HIV-2 Antibody Test to validate the correct performance of the test procedure in the hands of the operator.

The INSTI HIV-1/HIV-2 Positive Controls are prepared from inactivated human plasma. It is negative for HBsAg and anti-HCV by U.S. FDA licensed test procedures.

The Positive Controls have 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/HIV-2 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:

HIV-1 POSITIVE CONTROL (90-1031, 90-1030)
1 vial containing 1.0 ml of inactivated human plasma. Each vial is sufficient for 20 INSTI tests. The source material has been heat inactivated at 60°C for 60 minutes.

HIV-2 POSITIVE CONTROL (90-1031)
1 vial containing 1.0 ml of inactivated human plasma. Each vial is sufficient for 20 INSTI tests. The source material has been heat inactivated at 60°C for 60 minutes.

NEGATIVE CONTROL (90-1031, 90-1030)
1 vial containing 1.0 ml of processed human serum substitute, non-reactive for antibodies to HIV and HCV and non-reactive for HBsAg. Each vial is sufficient for 20 INSTI tests.

WARNINGS & PRECAUTIONS
- **For *in vitro* diagnostic use only**. IVD

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:
Do not use INSTI HIV-1/HIV-2 Test 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. The INSTI HIV-1/HIV-2 Test Controls are shipped without temperature control. Upon receipt, store frozen at -20°C (-4°F) for up to one year or refrigerate at 2°C (36°F) to 8°C (46°F) for up to one year.
2. The shelf life is dictated by the printed expiry date on the INSTI Test Controls.
3. It is recommended to store the vials in an upright position.
4. Once the controls are thawed continue storage at refrigeration temperatures (2-8°C). They remain stable until expiry (up to 1 year). Do not re-freeze once the vials have been opened.
5. Fluctuations in temperature causing freeze-thaw cycles may affect the performance of the INSTI Test Controls.

PROCEDURE
Materials Required but not Provided
- Pipette capable of delivering 50µl of specimen.
- INSTI HIV-1/HIV-2 Antibody Test Package Insert.

Instructions for use
1. Read the INSTI HIV-1/HIV-2 Test Controls Package Insert prior to using the INSTI HIV-1/HIV-2 Test Controls.
2. Remove from storage at -20°C (-4°F) to 8°C (46°F) and allow the Controls to reach room temperature before testing with INSTI. Return Controls to refrigeration storage at 2-8°C after use.
3. Mix the Controls by swirling before use.
4. Uncap the HIV-1 Positive, HIV-2 Positive or Negative Control vial. Using a 50µl pipette, collect 50µl of the 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/HIV-2 Antibody Test Package Insert.
7. All Controls should be tested in the same manner as patient samples.
8. The HIV-1 Positive Control, HIV-2 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/HIV-2 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/HIV-2 Test Controls are only validated for use with the INSTI HIV-1/HIV-2 Antibody Test.
1. The TEST PROCEDURE and INTERPRETATION OF RESULTS sections of the INSTI HIV-1/HIV-2 Antibody Test package insert must be adhered to when testing the INSTI HIV-1/HIV-2 Test Controls.
2. Deviations from the procedure outlined in the INSTI HIV-1/HIV-2 Antibody Test Package Insert may produce unreliable results.
3. Do not dilute the INSTI HIV-1/HIV-2 Test Controls. The INSTI HIV-1/HIV-2 Test 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 HIV-1 Positive Control and HIV-2 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/HIV-2 Test 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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INSTI® HIV-1/HIV-2 Test Controls - Shipping and Storage Conditions

INSTI HIV-1/HIV-2 Test Controls consist of an artificial human plasma matrix supplemented with anti-HIV antibodies. The **INSTI® HIV-1/HIV-2 Test Controls** have a shelf life of 12 months at both frozen (-20°C; -4°F) and refrigerated (2°C to 8°C; 36°F to 46°F) temperatures and a shelf life of 14 days at ambient temperatures (15°C to 30°C; 59°F to 86°F). Both the anti-HIV antibodies and the plasma matrix that make up the Controls are very robust, having to withstand temperatures during manufacture of 60°C (±2°C) (140°F (±3.6°F) for 60-65 mins, and the Controls have been demonstrated to withstand repeated freeze-thaw cycles.

INSTI HIV-1/HIV-2 Test Controls are shipped by courier at ambient temperature within an insulated container containing a freezer gel pack. It is not unusual for the gel pack to have thawed and be at ambient temperature when the shipment arrives. This does not mean the INSTI Controls have been compromised; the INSTI Controls should be placed at the desired long term storage conditions (i.e. fridge or freezer) as soon as possible upon receipt.

bioLytical® Laboratories Inc. has conducted various stability studies on the **INSTI HIV-1/HIV-2 Test Controls** to ensure acceptable test performance upon exposure to various temperatures including a rigorous shipping stress study carried out as per ASTM D4169-09 guidelines at low (-29°C (±2°C) (-20°F (±3.6°F) for 36 hours), ambient (15°C to 30°C; 59°F to 86°F for 72 hours), and high (38°C (±2°C) (100.4°F (±3.6°F) for 36 hours) temperature stresses. Results of these studies support no impact on INSTI test performance up to 12 months post-exposure. Excursions encountered outside of these stated temperatures and exposure times have not been evaluated for long-term test performance.

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