The INSTI™ HIV-1/HIV-2 Antibody Test Kit

Single-use rapid assay for the detection of antibodies to Human Immunodeficiency Virus Type 1 and Type 2 (HIV-1/HIV-2)

Store at 15-30°C, 59-86°F. For in vitro diagnostic use only.

Read the entire Package Insert prior to beginning the test procedure. 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.

COMPLEXITY: WAIVED
For Fingerstick Whole Blood.

Any modification by the laboratory to the INSTI test or the FDA approved INSTI test 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.

MATERIALS PROVIDED
The INSTI™ HIV-1/HIV-2 Antibody Test kits are available in the following packaging formats:

- Outer box (24 kits) or full pouch (single test)
- Individually-Pouched Membrane Units (prepared with one control and one test reaction spot)
- Solution 1: Vial, Sample Diluent (each vial contains 1.5 ml of a Tris-Glycine buffered solution containing gel lytic agents and an anticoagulant agent)
- Solution 2: Vial, Color Developer (each vial contains 1.5 ml of a buffered protein solution containing a blue dye color indicator and an anticoagulant agent)
- Solution 3: Vial, Clarifying Solution (each vial contains 1.5 ml of a Tris-Glycine buffered solution containing a detergent and an anticoagulant agent)
- Single Use Safety Lancet
- Specimen Collection Capillary
- Pipette with 50μl line
- Single Use 3%/70% Isopropyl Alcohol Swab
- General Information Brochure
- Customer Letter
- Package Insert

COMPLEXITY: MODERATE
For Venous Whole Blood and Plasma Samples

NAME AND INTENDED USE:
The INSTI™ HIV-1/HIV-2 Antibody Test is a single use, rapid, in vitro qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 and/or Type 2 (HIV-1 and/or HIV-2) in venous whole blood, fingerstick blood, or plasma specimens. The test is intended for use by trained personnel in point of care and laboratory situations to aid in the diagnosis of HIV infections. If multiple rapid HIV tests are available, this test is suitable for use in appropriate multi-test algorithms.

RESTRICTIONS
- Sale of the INSTI™ HIV-1/HIV-2 Antibody Test is restricted to clinical laboratories.
- The package insert must be available to the operator of the clinical laboratory.
- The package insert is intended for use by trained personnel in point of care and laboratory situations.
- The INSTI™ HIV-1/HIV-2 Antibody Test is approved for use only by an agent of a clinical laboratory.
- Tests subjects must receive the "Subject Information" brochure prior to specimen collection and appropriate counselling when test results are provided.

SUMMARY AND EXPLANATION OF THE TEST
Acquired Immunodeficiency Syndrome (AIDS) is thought to be caused by at least two retroviruses, Human Immunodeficiency Virus Type 1 (HIV-1) and Human Immunodeficiency Virus Type 2 (HIV-2). HIV-1 and HIV-2 are similar in genomic structure, morphology and ability to cause AIDS. HIV is transmitted mainly by sexual contact, exposure to blood or blood products (including sharing contaminated needles and syringes), or from an infected mother to her fetus. People with increased risk of HIV infection include hemophiliacs, intravenous drug users and men having sex with men (MSM). HIV has been isolated from patients with AIDS, AIDS-related complex (ARC) and from asymptomatic HIV infected persons. Antibodies specific for HIV envelope proteins are prevalent in blood or blood products from persons at high risk of contracting AIDS as well as in people with AIDS, or ARC. The presence of antibodies to HIV indicates previous exposure to the virus, but does not necessarily constitute a diagnosis of AIDS. The prevalence of antibodies to HIV in people known to be at risk of acquiring HIV infection is unknown, but significantly less. Absence of antibodies to HIV does not indicate an individual is absolutely free of HIV-1 or HIV-2; HIV has been isolated from seronegative individuals prior to seroconversion. Test specificity and sensitivity depend, among other factors, on: the selection of HIV antigens used for antibody detection, the classes of antibodies recognized by the detection conjugate, and the complexity of the protocol used to perform the test. Non-specific reactions may be observed in some specimens.

The INSTI™ HIV-1/HIV-2 Antibody Test can be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in point of care settings. Using a rapid HIV test provides an opportunity to identify more seroconverters, and it is recommended in facilities that have a high risk of infection.

MATERIALS REQUIRED AND AVAILABLE AS AN ACCESSORY TO THE KIT
- INSTI™ HIV-1/HIV-2 Antibody Test Kit Controls (product 80-1071): Each package of INSTI™ controls contains separate HIV-1 (12 vials, red caps), HIV-2 (12 vials, orange caps) Controls, and HIV Negative Controls (12 vials, green caps, 0.4 ml per vial), and a Package Insert.

MATERIALS REQUIRED BUT NOT PROVIDED
- Personal protective equipment such as gloves, lab coat or gown.
- Absorbent cotton for fingerstick or venipuncture wound closure.
- Appropriate biohazard waste containers.
- Precision pipette capable of delivering 50μl of specimen.
- Venipuncture apparatus if collecting blood specimens.
- Venipuncture apparatus if collecting blood specimens.
- Venipuncture apparatus if collecting blood specimens.
- Venipuncture apparatus if collecting blood specimens.
- Appropriate blood collection tubes.
- Personal protective equipment.
- Appropriate biohazard waste containers and disinfectants.
- Centrifuge to process a plasma specimen.

WARNINGS
For in vitro diagnostic use only
1. Read the entire Package Insert prior to beginning the test procedure. Complete conformance with the test procedure is necessary to ensure accurate results.
2. Before performing testing, operators must read and 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.
3. Do not use the Membrane Unit if the foil pouch has been previously opened or if the packaging integrity of any component has been compromised. Once the Membrane Unit has been opened, it must be used immediately.
4. Sodium azide is present at 0.1% in all assay reagents. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. If present, containing sodium azide are discarded into a drain, flush with large amounts of water to prevent azide build-up. Check with local regulatory agencies to determine at what concentration sodium azide may cause a product to be regulated as hazardous.
5. The performance characteristics of the INSTI™ HIV-1/HIV-2 Antibody Test have not been established for body fluids other than venipuncture whole blood, fingerstick blood, and plasma. Insufficient data are available to interpret tests performed on other body fluids, pooled blood plasma, or products made from such pools.
6. If the test kit is exposed to temperatures outside of 15 – 30°C, (59 – 86°F), ensure it is brought to this temperature range before performing testing. Use the INSTI™ Controls to ensure proper kit performance.
7. Patients that are receiving highly active antiretroviral therapy (HAART) may have undetectable levels of antibody to HIV-1 and/or HIV-2 and may have a false Non-Reactive INSTI™ HIV-1/HIV-2 Antibody Test result.
8. Specimens from patients with multiple myeloma, may result in false Non-Reactive or invalid results with the INSTI™ HIV-1/HIV-2 Antibody Test.
9. Patients with elevated hemoglobin levels may test false Non-Reactive with the INSTI™ HIV-1/HIV-2 Antibody Test.
5. Transfer the blood held in the pipette to the Sample Diluent vial (Solution 1). Align the tip of the pipette with the Sample Diluent vial and squeeze the bulb to dispense the specimen. Note: If the specimen will not expel, hold the pipette vertically and slide a finger over (without pressing) the vent to cause the specimen to expel. Capillary action automatically draws the specimen to the black fill line and stops.

6. Avoid forming aerosols.

7. Dispose of all specimens and materials used to perform the test in a biohazard waste container.

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” and “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis”.

Handling Precautions

1. Use all alcohol swabs, safety lancets, capillary pipette, INSTI™ solution vials and membrane units only once and dispose of properly (see Safety Precautions). Do not reuse any of these test components.

2. Do not mix reagent vials and membrane units from different lots.

3. Do not use the test beyond the expiration dates printed on the outer packaging, reagent vials and membrane unit pouch.

4. Avoid microbial contamination and exercise care in handling the kit components.

5. All Membrane Units must be used immediately in the test procedure once the membrane unit pouch is opened.

6. When collecting fingertip blood with the capillary pipette, ensure blood flows to the black fill line. Do not squeeze the capillary pipette bulb while collecting the specimen. (See Test Procedure).

STORAGE INSTRUCTIONS

Store unused INSTI™ kits unopened at 15°-30°C, 59°-86°F. Do not open the Membrane Unit pouch until ready to use.

INSTRUCTIONS FOR USE

Workplace Preparations

- Ensure the workspace is clean and uncluttered. Preferably, cover the workspace with a clean, disposable absorbent workspace cover.

- Gather support materials (swab, lancet, pipette), one sealed test pouch containing INSTI™ Membrane Unit, and one vial each of the Sample Diluent, Color Developer, and Clarifying Solution for each test to be performed.

- Gather the required materials you will need.

- Refer to the External Quality Control section of this package insert to determine when INSTI™ Controls should be run.

- Put on the gloves and any other personal protective equipment as required in accordance with the Safety Precautions section of this package insert.

Prior to testing provide the “Subject Information” brochure to the individual being tested.

SPECIMEN COLLECTION AND TESTING PROCEDURE

The INSTI™ HIV-1/HIV-2 Antibody Test can be used for testing fingertip whole blood, venipuncture whole blood and plasma specimens.

Fingertip Whole Blood:

Caution: The amount of specimen (fingertip blood) is critical. To ensure that the proper amount of blood is achieved, follow these instructions carefully:

1. Massage the finger to allow the blood to move to the surface (fingertip will become pink). Use heating pad if available to warm the hand. Hand should be positioned at waist level or lower for optimal blood flow.

2. Wipe the fingertip with the alcohol swab.

3. As soon as the finger is dry, twist and remove the protective tab from the lancet (Figure A). Grasp the finger firmly at the point just below where the lancet will be applied. With the other hand, hold the lancet firmly, depress the tip of the lancet on the finger and then push down to release the needle (Figure B). Immediately dispose the used lancet into a proper sharps container.

4. As the ooze soothes up, now cap the capillary pipette noncorrosively and snap the tip on to the pipette to the blood specimen. Capillary action automatically draws the specimen to the black fill line and stops. If very little blood trickles out of the puncture, gently apply intermittent pressure near the puncture site to obtain the required blood volume. If the volume of blood is inadequate, perform a second finger puncture using a new lancet and capillary pipette.

Follow the Test Procedure, below.

Venipuncture Whole Blood

1. Using standard venous phlebotomy procedures, collect a whole blood specimen in a tube containing any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), sodium citrate (light blue top). Other anticoagulants have not been validated and may give an incorrect result.

2. Do not test at the time of specimen collection, whole blood specimens may be stored for up to 5 days at 2-24°C. Prior to testing, mix the blood by gentle inversion several times. Do not heat or freeze whole blood specimens.

3. Using a calibrated 50μl precision pipette and clean unused tip, collect 50μl of whole blood from the collection tube.

4. Transfer the blood held in the pipette to the Sample Diluent vial (Solution 1). Recap the vial and mix by inversion. Follow the Test Procedure, below.

Plasma

1. Using standard venous phlebotomy procedures, collect a whole blood specimen in a tube containing any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), sodium citrate (light blue top). Other anticoagulants have not been validated and may give an incorrect result.

2. Centrifuge the tube of blood at 1000-1200 x g for approximately 5 minutes to separate the blood cells from the plasma. Plasma will be stored at 2-24°C for up to 5 days prior to testing. Carefully uncap the tube so as not to produce any aerosols.

3. Using a calibrated 50μl precision pipette and clean unused tip, collect 50μl of the separated plasma from the collection tube.

4. Transfer the plasma held in the pipette to the Sample Diluent vial (Solution 1). Recap the vial and mix by inversion. Follow the Test Procedure, below.

TEST PROCEDURE

Note: All components for the INSTI™ HIV-1/HIV-2 Antibody Test are ready to use as supplied. All Membrane Units must be used immediately once opened. All reagents should be dispensed evenly in the center of the well.

For Testing Fingertip Whole Blood, Venipuncture Whole Blood, Plasma and INSTI™ Controls:

1. Tear open the pouch and carefully remove the Membrane Unit without touching the center well. Place the unit on a level surface. For specimen identification purposes the tab of the Membrane Unit may be labeled with the patient’s name or number.

NOTE: At this point, it is important that the following steps be performed immediately and in sequence.

2. Mix the Sample Diluent-specimen mixture by inverting several times and pour the entire contents to the center of the Membrane Unit well. (Note: Do this within 5 minutes after the specimen has been added to the Sample Diluent vial). The Sample Diluent-specimen mixture should be absorbed through the membrane in less than 30 seconds; however, absorption times will vary slightly depending upon specimen type. (see Note, below)

3. Re-suspend the Color Developer by slowly inverting to mix the solution thoroughly, until the reagent is evenly suspended. Open the Color Developer and add the entire contents to the center of the Membrane Unit well. The colored solution should flow through completely in about 20 seconds.

4. Open the Clarifying Solution and add the entire contents to the center of the Membrane Unit well. This will reduce the background color and facilitate reading; immediately read the result while the membrane is still wet. Do not read the results if more than 5 minutes has elapsed following the addition of Clarifying Solution.

Note: If at the any period during Test Procedure steps 2, 3, or 4 the solutions completely stop flowing into the Membrane Unit, the procedure must be halted, a new specimen collected, and the procedure re-started from the beginning with fresh INSTI™ components.

QUALITY CONTROL

Procedure Control

The INSTI™ HIV-1/HIV-2 Antibody Test has a built-in procedure control that demonstrates assay validity and adequate specimen addition. A blue color in the control spot indicates that the proper specimen was added and that the test procedure was performed correctly. The control spot must appear on all valid INSTI™ tests. (Refer to Interpretation of Results in this package insert.)

External Quality Control

INSTI™ HIV-1/HIV-2 Antibody Test Kit Controls are available separately for use only with the INSTI™ HIV-1/HIV-2 Antibody Test. The controls are used to verify test performance and interpretation of results. The Positive Controls and the Negative Control are to be run on separate Membrane Units. The HIV-1 and HIV-2 Positive Controls have been manufactured to produce a faint blue color in the test spot.

CAUTION! Filling is automatic: Never squeeze the pipette while sampling.

5. Transfer the blood held in the pipette to the Sample Diluent vial (Solution 1). Align the tip of the pipette with the Sample Diluent vial and squeeze the bulb to dispense the specimen. Note: If the specimen will not expel, hold the pipette vertically and slide a finger over (without pressing) the vent hole, then squeeze the bulb (see illustrations below). Recap the vial and mix by inversion.
Negative Control will produce a blue color in the control spot, but no color in the test spot, for a Non-Reactive test result. Use of non-validated kit control material manufactured by other sources may not produce the required results and therefore would be inadequate for quality assurance programs for the INSTI™ HIV-1/HIV-2 Antibody Test.

INSTI™ HIV-1/HIV-2 Positive and Negative Controls should be run under the following circumstances:

- For new INSTI™ operator verification prior to performing the test 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 assay area outside falls of 15°-30°C (59°-86°F)
- At regular intervals as determined by the user facility.

INTERPRETATION OF RESULTS

- Do not read the results if more than 5 minutes has elapsed following the addition of sample diluents to the test kit components.
- If using the controls provided by bioLytical, 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™. If results are still incorrect or invalid, inform bioLytical Laboratories immediately.
- Follow CDC guidelines to inform the test subject of the Test Result and its interpretation [additional reference (see Bibliography)].

NON-REACTIVE

- Only the control spot shows blue color development. The visible control spot indicates that the test has been performed correctly and a proper specimen was added. As illustrated, the control spot is located towards the top of the test card furthest from the plastic tab on the Membrane Unit. No blue spot should be visible at the test spot, located below the control. A Non-Reactive result indicates that antibodies to HIV-1 and/or HIV-2 were not detected in the specimen.

SECONDARY RESULTS

- Reactive: Both the control spot and the test spot show blue color development. This Reactive test result indicates that the specimen is preliminary positive for HIV antibodies. As illustrated, one spot may be darker than the other.
- Non-Reactive: The test result is invalid if any of the following occur:
  - A. There is no blue color on the control spot or the test spot
  - B. There is blue color on the test spot but not on the control spot
  - C. Uniform tint across the membrane
  - D. Only blue specks appear on the membrane

Invalid test results means that the test was run incorrectly or insufficient specimen was added. Invalid test results cannot be interpreted. Repeat test with a fresh specimen using a new Membrane Unit, kit components and support materials. Contact bioLytical Laboratories’ Technical Support if you are unable to produce a valid result upon repeat testing.

LIMITATIONS OF THE TEST

1. The INSTI™ HIV-1/HIV-2 Antibody Test must be used in accordance with the instructions in this package insert to obtain accurate results.
2. In some instances, specimens may exhibit longer than normal flow times (from the time the Sample Diluent specimen mixture is poured in the membrane well to the time the Clariﬁng Solution has fully ﬂowed through the membrane). This is due to variable factors such as cellular components, especially with whole blood. As long as the contents from all three INSTI™ solution tubes completely ﬂow through the membrane, regardless of ﬂow time, the test can be properly interpreted according to the interpretation of Results section of this package insert. In occasional instances of long flow times, a faint result in the form of a ring may appear at the test spot location. This should be considered as a Reactive result.
3. For a Reactive result, the intensity of the test spot does not necessarily correlate with the titer of antibody in the specimen.
4. The test is approved by FDA for use with ﬁngerstick whole blood, venipuncture whole blood, and plasma specimens only. Other specimen types have not been evaluated and may give incorrect results.
5. Use of other anticoagulants not listed in the Specimen Collection and Testing Procedure for Venipuncture Whole Blood and Plasma section of this package insert has not been evaluated and may give incorrect results.
6. Reading the test results after more than 5 minutes has elapsed following the addition of Clariﬁcation Solution might produce erroneous results.
7. The INSTI™ HIV-1/HIV-2 Antibody Test detects antibodies to HIV-1 and/or HIV-2 and is useful as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. Because a variety of factors may cause non-specific reactions, a patient found to be Reactive using the INSTI™ HIV-1/HIV-2 Antibody Test should have a blood specimen drawn for laboratory-based conﬁrmatory testing. A person who has antibodies to HIV is presumed to be infected with the virus and appropriate counseling and medical evaluation should be offered. The presence of HIV antibodies indicates past exposure to HIV but is not a diagnosis of AIDS, which can only be made by a physician. However, a Non-Reactive test does not rule out past exposure to HIV.
8. Patients that are receiving highly active antiretroviral therapy (HAART) may have undetectable levels of HIV antibodies and give a false Non-Reactive INSTI™ HIV-1/HIV-2 Antibody Test result.
9. Specimens from patients with multiple myeloma, may result in false Non-Reactive or invalid results with the INSTI™ HIV-1/HIV-2 Antibody Test.
10. Patients with elevated hemoglobin levels may test false Non-Reactive with the INSTI™ HIV-1/HIV-2 Antibody Test.
11. A person who has antibodies to HIV is presumed to be infected with the virus, except 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 counseling, medical evaluation, and possibly additional testing to determine whether a diagnosis of HIV infection is accurate.

PERFORMANCE CHARACTERISTICS

SENSITIVITY: DETECTION OF ANTIBODIES TO HIV-1 IN SPECIMENS FROM HIV-1 INFECTED INDIVIDUALS

A sensitivity study was performed in 14 clinical trial sites using freshly obtained matching fi ngerstick whole blood, EDTA whole blood, and EDTA plasma specimens collected from 1076 individuals known to be infected with HIV-1. Additionally, matching fingerstick whole blood, EDTA whole blood, and EDTA plasma specimens were collected from 782 previously unscreened individuals from populations at high risk for HIV-1 from which 22 were confirmed seropositive by an FDA licensed test. For the 1098 total HIV-1 positives, results for fingerstick whole blood, venipuncture whole blood and plasma are shown in Tables 2, 3 and 4.

Table 1

Detection of Antibody to HIV-1 in Fingerstick Whole Blood Specimens from Seropositive Individuals and Individuals at High Risk of HIV Infection

<table>
<thead>
<tr>
<th>Test Group</th>
<th>Total Specimens</th>
<th>Reactive</th>
<th>Non-Reactive</th>
<th>Reactive</th>
<th>Non-Reactive</th>
<th>Reactive</th>
<th>Non-Reactive</th>
<th>Approved Test Result</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known HIV-1 Positive</td>
<td>1075</td>
<td>1074</td>
<td>1</td>
<td>0</td>
<td>1074</td>
<td>0</td>
<td>1075</td>
<td>0</td>
<td>1075</td>
</tr>
<tr>
<td>High Risk</td>
<td>1095</td>
<td>1094</td>
<td>1</td>
<td>0</td>
<td>1094</td>
<td>0</td>
<td>1095</td>
<td>0</td>
<td>1095</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2170</td>
<td>2168</td>
<td>2</td>
<td>0</td>
<td>2168</td>
<td>0</td>
<td>2170</td>
<td>0</td>
<td>2170</td>
</tr>
</tbody>
</table>

1. Invalid results were not included in the calculation of sensitivity. The 4 specimens which gave invalid results on INSTI™ were Non-Reactive on the approved test.
2. Confirmed by licensed HIV-1 Western Blot
3. Of the 22 true positive specimens, 1 was Non-Reactive on INSTI™ (false Non-Reactive). One other specimen was false Reactive on INSTI™.

Fingerstick Whole Blood Specimens

Of the 1076 known HIV-1 positive individuals, one did not provide a fingerstick specimen. Of the 1075 fingerstick specimens from the known HIV-1 positive patients that were repeatedly Reactive by an FDA licensed test, 1074 gave Reactive result with INSTI™. Within the high risk population, 22 patients were confirmed seropositive by an FDA licensed test and of those, 21 were Reactive with INSTI™. One specimen was false Non-Reactive on INSTI™. One additional fingerstick specimen from the same patient was repeatedly Reactive on INSTI™. The overall sensitivity of the INSTI™ HIV-1/HIV-2 Antibody Test in fingerstick whole blood specimens for the confirmed HIV-1 positive specimens from the combined high risk and known HIV-1 positive populations was calculated to be 1095/1097= 99.8% (95% CI = 99.3% - 99.9%). The rate of invalid tests was 4/1857 (0.2%).

Table 2

Comparison of Results for Fingerstick Whole Blood Specimens from Seropositive Individuals and Individuals at High Risk of HIV Infection

<table>
<thead>
<tr>
<th>INSTI™ Test Result</th>
<th>Reactive</th>
<th>Non-Reactive</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive</td>
<td>1065</td>
<td>1</td>
<td>1066</td>
</tr>
<tr>
<td>Non-Reactive</td>
<td>4</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1069</td>
<td>5</td>
<td>1074</td>
</tr>
</tbody>
</table>

1. The one specimen that gave a false Reactive result on INSTI™ was from an individual at high risk for HIV infection.
2. Of the two false Non-Reactive specimens on INSTI™, one was from an individual known to be HIV-1 infected and one was from an individual at high risk for HIV infection.

Table 3

Detection of Antibody to HIV-1/HIV-2 in Venipuncture Whole Blood Specimens from Seropositive Individuals and Individuals at High Risk of HIV Infection

<table>
<thead>
<tr>
<th>INSTI™ Test Result</th>
<th>Reactive</th>
<th>Non-Reactive</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive</td>
<td>1096</td>
<td>1</td>
<td>1097</td>
</tr>
<tr>
<td>Non-Reactive</td>
<td>6</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1098</td>
<td>7</td>
<td>1105</td>
</tr>
</tbody>
</table>

1. Of the 1076 known HIV-1 positive EDTA whole blood specimens, 1075 gave Reactive results with INSTI™. Within the high risk group, 22 EDTA whole blood specimens were confirmed seropositive by an FDA licensed test and these same 22 were Reactive with INSTI™. The overall sensitivity of the INSTI™ HIV-1/HIV-2 Antibody Test in venipuncture whole blood specimens for the confirmed HIV-1 positives was calculated to be 1075/1097= 97.8% (95% CI = 97.3% - 98.3%).
and these same 22 were Reactive with INSTI™. Of the 1076 known HIV-1 positive EDTA plasma specimens, 1075 gave Reactive results with INSTI™. Plasma Specimens

PRB945, PRB947, PRB950, PRB952, PRB929, PRB934, PRB935, BRB937, PRB938, PRB940, PRB941, PRB943, PRB944, PRB945, PRB947, PRB950, PRB952.

The last bleed in the panel PRB937 was positive by at least 1 EIA, negative by INSTI™. Detection of Anti-HIV-1 non-B Subtypes
To assess the sensitivity of the INSTI™ HIV-1/HIV-2 Antibody Test for detection of antibodies to non-B subtypes of HIV-1, a total of 207 serum/plasma specimens collected from individuals from various geographic regions who were infected with non-B subtypes of HIV-1 were tested. Of these 207 specimens, a total of 206 were Reactive with the INSTI™ HIV-1/HIV-2 Antibody Test, for an overall sensitivity of 99.9% (95% CI = 99.5%-100%). One subtype A specimen tested false Non-Reactive. The INSTI™ results and HIV-1 non-B subtype listings are presented in Table 5 below.

Reactivity With HIV-1 Seroconversion Panels
Twenty three commercial seroconversion panels were tested and the INSTI™ results were compared with FDA licensed or approved anti-HIV EIA’s. The results of this study are shown in Table 6. In this study, the INSTI™ HIV-1/HIV-2 Antibody Test demonstrated the ability to detect HIV-1 antibodies during seroconversion similar to FDA licensed or approved anti-HIV EIA’s.

Table 5:
Sensitivity of the INSTI™ HIV-1/HIV-2 Antibody Test for Detection of Antibodies to HIV-1 Non-B Subtypes

<table>
<thead>
<tr>
<th>HIV Subtype</th>
<th>Number of Specimens</th>
<th>INSTI™ Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>28</td>
<td>27</td>
</tr>
<tr>
<td>C</td>
<td>57</td>
<td>57</td>
</tr>
<tr>
<td>D</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>F</td>
<td>9</td>
<td>9</td>
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<td>G</td>
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<td>H</td>
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<tr>
<td>AG1</td>
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</tr>
<tr>
<td>AG2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>207</td>
<td>206</td>
</tr>
</tbody>
</table>

Related Medical Conditions and Potentially Interfering Substances
To assess the impact of unrelated medical conditions or potentially interfering substances on the sensitivity of the INSTI™ HIV-1/HIV-2 Antibody Test, 196 serum/plasma specimens from a cross section of medical conditions unrelated to HIV infection and 217 specimens with potentially interfering substances were spiked with an HIV-1 positive specimen to give a low level of reactivity in the INSTI™ HIV-1/HIV-2 Antibody Test. The results are presented in Table 8.

Table 6:
HIV-1 Seroconversion Panel PRB-900 Series 1 Boston Biomedica Inc.

<table>
<thead>
<tr>
<th>INSTI™ HIV-1</th>
<th>Number of Panels (n=3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detect the earliest bleed that was detected by an EIA</td>
<td>18</td>
</tr>
<tr>
<td>Within 1 bleed of the earliest bleed that was detected by an EIA</td>
<td>4</td>
</tr>
<tr>
<td>Unknown1</td>
<td>1</td>
</tr>
</tbody>
</table>

1PRB904, PRB910, PRB914, PRB916, PRB919, PRB924, PRB925, PRB926, PRB927, PRB928, PRB929, PRB934, BRB937, PRB938, PRB940, PRB941, PRB943, PRB944, PRB945, PRB947, PRB950, PRB952.

The last bleed in the panel PRB937 was positive by at least 1 EIA, negative by INSTI™.

Reactivity With HIV-1 Low Titer Panel
One HIV-1 low titer panel was tested with 3 production lots of INSTI™ and results were compared to three FDA licensed or approved HIV EIA’s. The results of this study are shown in Table 7. In this study, the INSTI™ HIV-1/HIV-2 Antibody Test was capable of detecting levels of antibodies to HIV-1 HIV-1/19 similar to FDA licensed or approved EIA’s.

Table 7:
Comparison of the INSTI™ HIV-1/HIV-2 Antibody Test and Licensed or Approved Anti-HIV EIA Tests Using a Low Titer HIV-1 Antibody Panel.

<table>
<thead>
<tr>
<th>PANEL</th>
<th>MEMBER</th>
<th>INSTI™</th>
<th>EIA #1</th>
<th>EIA #2</th>
<th>EIA #3</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRB 100</td>
<td>1</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>2</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
</tbody>
</table>

1Identical INSTI™ results were obtained across the three production lots tested.

Related statements are listed in the Warnings and Limitations sections of this package insert.

In addition, a study was performed to assess the potential effect of common blood tube anticoagulants on assay sensitivity. Venipuncture blood was collected from 13 volunteer subjects in each of 3 tubes containing one of three anticoagulants (EDTA, sodium heparin, and sodium citrate). A total of 13 specimens for each anticoagulant type were spiked with an HIV-1 positive specimen to give a low level of reactivity in the INSTI™ HIV-1/HIV-2 Antibody Test. Aliquots of the spiked specimens were stored refrigerated (2 – 8 C) and at ambient temperature (20 – 24 C) and tested at day 3 and day 7 over a 7 day period. There was no effect of the anticoagulants on sensitivity with specimens held up to 7 days at room temperature. There was no effect of the anticoagulants on sensitivity with specimens held up to 7 days at room temperature. There was no effect of the anticoagulants on sensitivity with specimens held up to 7 days at room temperature.
Comparison of Results for Fingerstick Whole Blood Specimens from Low and Unknown Risk

INSTI™ results (see Table 9) were obtained from the 1382 specimens from HIV-negative individuals that produced valid results. Of the 22 INSTI Reactive specimens, one was Non-Reactive by the approved test, i.e. INSTI™ false specificity. 1 Invalid results were not included in the calculation of specificity. The 4 specimens which gave invalid results by the differentiation assay or an HIV-2 RNA quantitative assay1b, INSTI was reactive in all 12 of these specimens. The results are presented in Table 9. In the combined specimen groups, a total of 202 specimens were confirmed reactive for HIV-2 only, by the FDA-approved differentiation assay or by an HIV-2 RNA quantitative assay1c. INSTI was reactive on 201/202 of these specimens for a calculated sensitivity of 99.5% (95% CI = 97.2% - 99.9%).

SPECIFICITY:
A specificity study was performed in the same 14 clinical trial sites using freshly obtained matching fingerstick whole blood, EDTA whole blood, and EDTA plasma specimens collected from 1410 low or unknown risk and high risk individuals. Of the 1388 individuals identified as HIV negative using an approved comparator assay, 2 did not provide a fingerstick specimen. Of the remaining 1386 fingerstick specimens, 1376 gave a Non-Reactive result with INSTI™, and 4 were invalid. Within the high risk group, 22 specimens were confirmed seropositive by Western Blot and of those, 21 were Reactive with INSTI™; an additional high risk specimen (1/22) was INSTI™ false Reactive. Of the 1385 matching EDTA whole blood and plasma specimens, 1388 gave Non-Reactive results with INSTI™. Results are shown in Tables, 10, 11, 12, 13, and 14.

Table 10 Performance of the INSTI™ HIV-1/HIV-2Antibody Test on Fingerstick Whole Blood Specimens from Individuals Presumed to be HIV Negative and Individuals at High Risk of HIV Infection

<table>
<thead>
<tr>
<th>INSTI™ Group</th>
<th>Total Specimens</th>
<th>INSTI™ Non-Reactive</th>
<th>INSTI™ Reactive</th>
<th>INSTI™ Invalid</th>
<th>Approved Test Non-Reactive</th>
<th>Approved Test Reactive</th>
<th>True Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low or Unknown Risk</td>
<td>1376</td>
<td>1376</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1384</td>
<td>1384</td>
</tr>
<tr>
<td>High Risk</td>
<td>22</td>
<td>22</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1398</td>
<td>1398</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1406</td>
<td>1406</td>
</tr>
</tbody>
</table>

Invalid results were not included in the calculation of specificity. The 4 specimens which gave invalid results by the differentiation assay or an HIV-2 RNA qualitative assay1b, INSTI was reactive in all 12 of these specimens.

Unrelated Medical Conditions and Potentially Interfering Substances
To assess the impact of unrelated medical conditions or potentially interfering substances on the specificity of the INSTI™ HIV-1/HIV-2Antibody Test, 195 serum/plasma specimens from a cross section of medical conditions unrelated to HIV infection and 217 specimens with potentially interfering substances were tested with the INSTI™ HIV-1/HIV-2Antibody Test. The results are presented in Table 15.

In addition, a study was performed to assess the potential effect of common blood tube anticoagulants on assay specificity. Venipuncture blood was collected from 13 volunteer subjects in each of 3 tubes containing one of three anticoagulants (EDTA, sodium heparin, and sodium citrate). Aliquots of the spiked specimens were stored refrigerated (2 – 8 C) and at ambient temperature (20 – 24 C) and tested at day 3 and day 7 over a 7 day period. There was no effect of the anticoagulants on specificity with specimens held up to 7 days at 2 - 24 C. Results are shown in Table 15.

Table 15 INSTI™ HIV-1/HIV-2Antibody Test Specificity with Specimens from Individuals with Unrelated Medical Conditions (n=195) and with Specimens containing Potentially Interfering Substances (n=217)

<table>
<thead>
<tr>
<th>Unrelated Medical Condition (n=195)</th>
<th>No. of Specimens</th>
<th>INSTI™ Reactive</th>
<th>INSTI™ Non-reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxoplasmosis</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Rheumatoid Factor</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Multiple Myeloma</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Syphilis</td>
<td>30</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>SLE</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Rubella</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Cytomegalovirus</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Epstein Barr Virus</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>HTLV-III panel</td>
<td>15</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Hepatitis B Virus</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Hepatitis A Virus</td>
<td>15</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Potentially Interfering Substance (n=217)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Icteric</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Elevated Bilirubin (2-8mg/dL)</td>
<td>19</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>Lipemic</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Visual Hemolysis</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Elevated Triglyceride (&gt;250mg/dL)</td>
<td>19</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>Elevated Hemoglobin (&gt;12g/100mL)</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Elevated Albumin (11.5-13.5g/dL)</td>
<td>15</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>EVITA</td>
<td>13</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>13</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>13</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Bacterially Contaminated</td>
<td>60</td>
<td>60</td>
<td>0</td>
</tr>
</tbody>
</table>

1Up to 5 specimens from individuals with multiple myeloma produced invalid INSTI™ results depending on the INSTI™ kit lot tested. A related statement is listed in the Warnings and Limitations sections of this Package Insert.

Reproducibility
The reproducibility of the INSTI™ HIV-1/HIV-2Antibody Test was tested at 3 laboratory sites using 3 lots of the INSTI™ HIV-1/HIV-2Antibody Test on 3 separate days with 9 operators (3 per site). A panel of 5 blind-coded contrived plasma specimens, consisting of 4 HIV-1 antibody positive (one strong...
positive and three low positives) and 1 HIV-1 antibody negative specimen was tested at each site. A total of 405 tests were conducted, 135 at each site, with a total of 81 tests per panel specimen. The overall reproducibility of the INSTI™ HIV-1/HIV-2 Antigen Test was 405/405 = 100%.

CLIA WAIVER Study

The performance of the INSTI HIV-1/HIV-2 Antigen Test was evaluated in a prospective study conducted over 4 months at 3 geographically diverse sites located in Arizona, Pennsylvania, and Florida. At each site, INSTI testing was conducted by operators who had no laboratory experience and were not representative of users at CLIA waived testing sites (intended use). The 11 operators (intended users) who participated in the study were not given any training on the use of the test. There were 905 subjects with known HIV status. 483 subjects known to be HIV positive. The subjects with unknown HIV status were tested with INSTI and the comparator method. The subjects known to be HIV positive were tested with INSTI and their HIV status was not known to the operators. Fingerstick blood from each subject was compared. 95% of INSTI HIV status was tested with INSTI by the operators at each site. HIV status for each subject with unknown HIV status was determined by a composite reference method (comparator method) which consists of an FDA approved EIA with supplemental Western blot and PCR assays as required. The result of INSTI was compared with the HIV status of the subject. The positive percent agreement and negative percent agreement between INSTI and the HIV status for the study specimens is presented in Table 16 below. There were no INSTI HIV-1/2 invalid results reported.

### Table 16

<table>
<thead>
<tr>
<th>Study Population</th>
<th>Number of Subjects</th>
<th>Positive Percent Agreement</th>
<th>Negative Percent Agreement</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown HIV status</td>
<td>905 (483/483)</td>
<td>99.9%</td>
<td>N.A.</td>
<td>99.9%</td>
</tr>
<tr>
<td>Known HIV-1 Positive</td>
<td>483</td>
<td>100%</td>
<td>N.A.</td>
<td>100%</td>
</tr>
<tr>
<td>Total</td>
<td>1,388 (571/1388)</td>
<td>99.3%</td>
<td>99.9%</td>
<td>99.9%</td>
</tr>
</tbody>
</table>

### Table 17

<table>
<thead>
<tr>
<th>Study Population</th>
<th>Number of Subjects</th>
<th>Positive Percent Agreement</th>
<th>Negative Percent Agreement</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV status unknown</td>
<td>905 (483/483)</td>
<td>99.9%</td>
<td>N.A.</td>
<td>99.9%</td>
</tr>
<tr>
<td>HIV-1 Positive</td>
<td>483</td>
<td>100%</td>
<td>N.A.</td>
<td>100%</td>
</tr>
<tr>
<td>Total</td>
<td>1,388 (571/1388)</td>
<td>99.3%</td>
<td>99.9%</td>
<td>99.9%</td>
</tr>
</tbody>
</table>

Additionally, a study was conducted to evaluate the ability of untrained operators to detect HIV antibodies in weakly reactive samples. Randomly coded panels consisting of 4 wells of weakly reactive plasma control material and 4 wells of unknown HIV status with INSTI were tested at 3 intended use sites by 10 untrained operators (60 measurements in total per sample). The testing was done over 5 consecutive days with samples integrated into the daily workflow at each site. The samples were prepared from a dilution series of single HIV-1 positive plasma control material and represent INSTI results that are at, slightly above and slightly below the cutoff in this dilution series. The same panel was also tested by trained laboratory professionals to verify that the dilution series gave the expected reactivities.

D A total of 3 INSTI invalid results were obtained: 1 invalid for Weakly Reactive 3 sample and 2 invalids results.

### Table 17 Performance of the INSTI HIV-1/HIV-2 Antigen Test Run by Intended Users with Weakly Reactive Samples

<table>
<thead>
<tr>
<th>Sample</th>
<th>Dilution</th>
<th>Percent Reactive</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weakly Reactive 1a</td>
<td>1:600</td>
<td>88.3%</td>
<td>77.8% - 94.2%</td>
</tr>
<tr>
<td>Weakly Reactive 2a</td>
<td>1:800</td>
<td>80.0%</td>
<td>68.2% - 88.2%</td>
</tr>
<tr>
<td>Weakly Reactive 3a</td>
<td>1:1200</td>
<td>66.1%</td>
<td>53.4% - 76.9%</td>
</tr>
<tr>
<td>Weakly Reactive 4a</td>
<td>1:1600</td>
<td>34.5%</td>
<td>23.6% - 47.3%</td>
</tr>
</tbody>
</table>

### Technical Information

For further information or assistance, or to report problems, contact biolitical Laboratories Technical Support / Customer Service at 1-866-674-6784.

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**BIBLIOGRAPHY**

11. World Health Organization/Global Programme on AIDS. Operational characteristics of commercially available assays to detect antibodies to HIV-1 and/or HIV-2 in human sera. Geneva, Switzerland; WHO documents: GABR/89.4, GABR/89.1.

**ADDITIONAL REFERENCE FROM INTERPRETATION SECTION:**


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