Human T-Lymphotrophic Virus Types I and II

Key to symbols used

- **REF**: List Number
- **LOT**: Lot Number
- **EXPIRATION DATE**: Expiration Date
- **IVD**: In Vitro Diagnostic Medical Device
- **CAUTION**: Consult instructions for use
- **ACTIVATOR DILUENT**: Activator Diluent
- **ACTIVATOR CONCENTRATE**: Activator Concentrate
- **QM**: Authorized Representative

Consult accompanying documents

Manufacturer

Activator Diluent

Activator Concentrate

U.S. License No. 43

ABBOTT PRISM HTLV-I/HTLV-II

List No. 6E50

34-4547/R2

ABBOTT LABORATORIES Diagnostics Division

Abbott Park, IL 60064

Customer Service

United States: 1-877-4ABBOTT

In Vitro Diagnostic Medical Device

Store at 2-8°C

Store at 15-30°C

Consult instructions for use

CAUTION: Consult accompanying documents

Activator Diluent

Activator Concentrate

Authorized Representative

U.S. License No. 43

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Authorized Representative
reported to be associated with HTLV-II infection.\textsuperscript{53-56} Epidemiologic data suggest nonserologic tests based on the presence of infected cells, or Tests based on reactivities to HTLV-I and HTLV-II type specific proteins may enable viral typing. Antibodies to HTLV-II in human serum or plasma are only occasionally related to the AIDS virus.\textsuperscript{\textsuperscript{57}} No cross-reactivity with antibodies to HIV-II has been demonstrated for this assay.\textsuperscript{\textsuperscript{57}} The specificity of the assay has no relation to the presence of antibodies to HIV-II. \textsuperscript{\textsuperscript{57}} Transmission of HTLV-I, like HTLV-II, occurs via transfusion of cellular blood components. HTLV-I endemic areas, 44 to 63\% of recipients seroconvert;\textsuperscript{\textsuperscript{44,31}} however, lower transmission of HTLV-II is endemic in the Caribbean,\textsuperscript{16} Japan,\textsuperscript{15} in some areas of Africa,\textsuperscript{\textsuperscript{23,24,12}} Central and South America.\textsuperscript{\textsuperscript{44,45,26}} In melanomas,\textsuperscript{\textsuperscript{26}} the Middle East\textsuperscript{\textsuperscript{26}} and central and northern Australia.\textsuperscript{\textsuperscript{23,24,12}} In the United States, HTLV-II has been identified in ATL patients, intravenous drug users, and in healthy individuals.\textsuperscript{1,2} Transmission of HTLV-II (and HTLV-I) infection to transfusion recipients of infected cellular blood products is well documented.\textsuperscript{\textsuperscript{30}} This assay also can occur in breastfeeding,\textsuperscript{\textsuperscript{38}} sexual contact,\textsuperscript{\textsuperscript{39,40}} and sharing of contaminated needles and syringes by intravenous drug users.\textsuperscript{\textsuperscript{41}}

HTLV-I is a new-world virus common among Amerindians in North, Central, and northern Australia.\textsuperscript{\textsuperscript{23,24,12}} In the United States, HTLV-I has been identified in intravenous drug users. \textsuperscript{\textsuperscript{36-39}} This assay can also occur in breastfeeding,\textsuperscript{\textsuperscript{38}} sexual contact,\textsuperscript{\textsuperscript{39,40}} and sharing of contaminated needles and syringes by intravenous drug users.\textsuperscript{\textsuperscript{41}}

Antibodies to HTLV-II in human serum or plasma are only occasionally related to the AIDS virus.\textsuperscript{\textsuperscript{57}} No cross-reactivity with antibodies to HIV-II has been demonstrated for this assay.\textsuperscript{\textsuperscript{57}} The specificity of the assay has no relation to the presence of antibodies to HIV-II. \textsuperscript{\textsuperscript{57}} Transmission of HTLV-I, like HTLV-II, occurs via transfusion of cellular blood components.
to the following:

- Avoid contact with skin.
- May cause sensitization by skin contact.

Clean and disinfect all spills of specimens or reagents using an appropriate disinfectant. Disinfect all surface areas where specimens or reagents are handled.

NOTE: This product contains human sourced and/or potentially infectious agents. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources will not transmit infection. Therefore, all human sourced materials used in this kit shall be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard for Occupational Exposure to Bloodborne Pathogens (29 CFR 1910.1030) and/or other appropriate blood-borne pathogen protection regulations. It is also recommended that the exposure of human blood and body fluids to workers in the health care setting be minimized as much as possible. In the course of performing work activities, it is recommended that all clinical laboratory workers and personnel who work with potentially infectious biological materials take appropriate precautions to protect themselves.


to measure. Refer to the ABBOTT PRISM Operations Manual Glossary for the definition of endpoints.

ABBOTT PRISM software version 3.12 or higher must be used to perform the assay.

For reference, refer to the ABBOTT PRISM Operations Manual, Section 8, under PREPARE AND LOAD ACTOR SOLUTION, for additional information.

- Use clean pipettes and/or metal-free containers (such as plasticware or acid-washed and purified or equivalent water-rinsed glassware) for dilution. Refer to the ABBOTT PRISM Operations Manual, Section 9, under STANDARD PROCEDURES. Refer to the ABBOTT PRISM Operations Manual, Section 10, for additional information.

ABBOTT PRISM Activator Concentrate (No. 1A74-04)

ABBOTT PRISM Operations Manual, Section 10, for additional information.

ABBOTT PRISM HTLV-I/HTLV-II Assay Kit, ABBOTT PRISM Positive Run Control Kit, and ABBOTT PRISM Activator Diluent, from room temperature (15-30°C) and then mixed before loading onto the ABBOTT PRISM System.

ABBOTT PRISM Pipette Tips and ABBOTT PRISM Reaction Trays in their storage containers. Do not mix reagents from different ABBOTT PRISM HTLV-I/HTLV-II Assay Kits.

ABBOTT PRISM HTLV-I/HTLV-II Wash Kit can be used with any lot of ABBOTT PRISM HTLV-I/HTLV-II Assay Kit.

ABBOTT PRISM Positive Run Control Kit (No. 3E60-10)

ABBOTT PRISM Positive Calibrator is reactive for anti-HTLV-I, and nonreactive for HBsAg, HIV-1 Ag or HIV-1 RNA, and HCV.

ABBOTT PRISM Positive Run Control Kit package insert or the ABBOTT PRISM Positive Run Control Kit package insert for additional handling and use instructions.

ABBOTT PRISM Activator Concentrate, Triton X-100, 0.2% diethylaminoethanol, phenol, 2% tetraethylammonium hydroxide (TEAH), may cause mild eye irritation. If the solution comes in contact with eyes, rinse immediately with water. For additional information, refer to the ABBOTT PRISM Operations Manual, Section 8.

ABBOTT PRISM HTLV-I/HTLV-II Conjugate Wash, Probe Wash and Biotinylated Probe contain methylisothiazolones (which are components of many biocides). Avoid contact with eyes, rinse immediately with water. For additional information, refer to the ABBOTT PRISM Operations Manual, Section 8.

ABBOTT PRISM HTLV-I/HTLV-II Assay Kit, ABBOTT PRISM Positive Run Control Kit, and ABBOTT PRISM Activator Diluent can be used with any lot of ABBOTT PRISM HTLV-I/HTLV-II Assay Kit. Close the bottle opening securely with the cap provided and invert gently five to ten times to mix. Load the Actor Solution on the ABBOTT PRISM System. Refer to the ABBOTT PRISM Operations Manual, Section 5, under PLAN WORK LOAD, for additional information. Use clean pipettes and/or metal-free containers (such as plasticware or acid-washed and purified or equivalent water-rinsed glassware) to measure. Refer to the ABBOTT PRISM Operations Manual Glossary for the definition of endpoints.

ABBOTT PRISM HTLV-I/HTLV-II Assay Kit contains sodium azide; for a specific listing, refer to the ABBOTT PRISM Operations Manual, Section 8.
SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS
Serum (including serum collected in separator tubes), plasma collected in EDTA, potassium oxalate, sodium citrate, ACD-A, ACD-B, CPD, CFD, or CPDA-1 anticoagulants, or plasma collected from heparinized tubing may be used with the ABBOTT PRISM HTLV-I/HTLV-II assay. Follow the manufacturer’s processing instructions for serum and plasma collection tubes.

CAUTION: Do not use specimens collected in heparin. Use of heparin as an anticoagulant may cause a reduction in Sample Net Counts and in Sample Net Counts/Control Value (S/CO) for ABBOTT PRISM HIV-1; therefore, heparin is not recommended for any ABBOTT PRISM assay.

This assay was designed and validated for use with individual human serum and plasma specimens. This assay has not been validated for use with pooled specimens.

Do not use heat-inactivated specimens.

Do not use specimens with obvious microbial contamination.

When shipped, specimens must be packaged and labeled in compliance with applicable regulations governing the transport of clinical specimens and infectious substances. Specimens may be shipped at 30°C or cooler for a period not to exceed 7 days. Prior to thawing, the serum or plasma should be removed from the clot or red blood cells.

Specimens may be stored for up to 14 days at 2-8°C. If storage periods greater than 14 days are anticipated, the serum or plasma should be removed from the clot or red blood cells to avoid hemolysis. Store the serum or plasma frozen (−20°C or cooler).

Previously frozen specimens must be mixed gently and thoroughly after thawing and centrifuged according to Table 1 in this section.

Twenty nonreactive and 40 low-level reactive specimens showed no qualitative performance differences when subjected to 5 freeze-thaw cycles. However, some specimens that undergo multiple freeze-thaw cycles have been stored frozen for protracted periods may give erroneous or inconsistent test results.

NOTE: Some specimens nonreactive for anti-HTLV-I and/or anti-HTLV-II that have been subjected to frozen storage have exhibited nonspecific reactivity in the ABBOTT PRISM HTLV-1/HTLV-2 assay.

Class II sensitized specimens should be used when possible. Specimens containing visible particulate matter may give erroneous or inconsistent test results.

No qualitative performance differences were observed when 20 nonreactive and 40 low-level reactive specimens were spiked with elevated levels of bilirubin (12-25 mg/dL), hemoglobin (≥150 mg/dL), red blood cells (≥5.4 x 10^11/L), or triglycerides (≥500 mg/dL); however, all specimens containing higher levels of bilirubin, hemoglobin, red blood cells, and triglycerides were nonreactive for anti-HTLV-I and/or anti-HTLV-II. Specimens containing greater concentrations of these potentially interfering substances have not been tested. The ABBOTT PRISM HTLV-1/HTLV-2 assay was made available to laboratories containing potentially interfering substances on the ABBOTT PRISM HTLV-1/HTLV-2 assay is unknown.

Performance has not been established using cadaveric specimens, umbilical cord blood, or body fluids such as urine, saliva, semen, amniotic fluid, cerebrospinal fluid, or placental fluid. These specimens should not be tested using the ABBOTT PRISM HTLV-1/HTLV-2 assay.

Specimens collected by plasmapheresis that have not been frozen do not require recentrifugation. All other specimens (including previously frozen plasmapheresis specimens) must be centrifuged as follows:

Non-frozen specimens (excluding non-frozen plasmapheresis specimens) must be centrifuged such that g-minutes is between 30,000 and 75,000. A refrigerated centrifuge will indicate the rpm.

Previously frozen specimens must be centrifuged such that g-minutes is between 180,000 and 300,000. A refrigerated or non-refrigerated centrifuge is acceptable for use. The acceptable time and force ranges that meet this criterion are listed in Table 2.

PREVIOUSLY FROZEN SPECIMENS

Failure to follow the specified centrifugation procedure may give erroneous or inconsistent test results.

Specimens volumes required to perform a single assay on the ABBOTT PRISM System vary according to the number and type of assays, and the different System models. For ABBOTT PRISM System X, the minimum specimen volume required for use with the ABBOTT PRISM HTLV-I/HTLV-II assay is 160 μL per test volume.

Failure to follow the specified centrifugation procedure may give erroneous or inconsistent test results.

Materials Provided

<table>
<thead>
<tr>
<th>No.</th>
<th>Material Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>6E53-03</td>
<td>ABBOTT PRISM HTLV-I/HTLV-II Wash Kit</td>
</tr>
<tr>
<td>6E53-04</td>
<td>ABBOTT PRISM Accessory Kit</td>
</tr>
<tr>
<td>6E53-05</td>
<td>ABBOTT PRISM Run Control Kit</td>
</tr>
<tr>
<td>6E53-06</td>
<td>ABBOTT PRISM Positive Run Control Kit</td>
</tr>
<tr>
<td>6E53-07</td>
<td>ABBOTT PRISM Pipette Tips</td>
</tr>
</tbody>
</table>
| 6E53-08 | ABBOTT PRISM Pipette Tips |}

Materials Required but Not Provided

- No. 6E53-01 ABBOTT PRISM Sample Cups
- Protective Disposable Gloves
- Disinfectant
- Purified Water-moist or Clean Disposable Measuring Equipment

ASSAY PROCEDURE

Key procedures for the process of testing samples that require operator interaction are listed below as reminders. For detailed information concerning batch-time, maximum batch size, sample handling and loading, and associated procedural steps, refer to the ABBOTT PRISM Operations Manual, Sections 6 and 7.

Enter a Plan Work Load (refer to the ABBOTT PRISM Operations Manual, Section 6).

Replace reagents as needed (refer to the ABBOTT PRISM Operations Manual, Sections 6 and 7).

NOTE: Gently invert each component 3 times prior to loading on the ABBOTT PRISM System to ensure a homogenous solution. Additional gentle inversion may be required to thoroughly suspend microparticles. Avoid foaming. Each component of the ABBOTT PRISM HTLV-I/HTLV-II Wash Kit should be at room temperature (15-30°C) and then mixed before loading onto the ABBOTT PRISM System.

### Table 1

<table>
<thead>
<tr>
<th>Centrifugation Time (minutes)</th>
<th>RCF (x g)</th>
<th>g-minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>3,000</td>
<td>30,000</td>
</tr>
<tr>
<td>15</td>
<td>3,000</td>
<td>45,000</td>
</tr>
<tr>
<td>20</td>
<td>3,000</td>
<td>60,000</td>
</tr>
</tbody>
</table>

Convert rpm to RCF as follows: RCF = \( \frac{0.32 \times \text{rpm}}{\text{max}} \) - 625

Convert rpm to g as follows: rpm = \( \frac{0.32 \times \text{RCF} + 625}{0.32 \times \text{RCF}} \)

### Table 2

<table>
<thead>
<tr>
<th>Centrifugation Time (minutes)</th>
<th>RCF (x g)</th>
<th>g-minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>8,000</td>
<td>160,000</td>
</tr>
<tr>
<td>25</td>
<td>7,200</td>
<td>180,000</td>
</tr>
</tbody>
</table>

NOTE: Gently invert each component 3 times prior to loading on the ABBOTT PRISM System to ensure a homogenous solution. Additional gentle inversion may be required to thoroughly suspend microparticles. Avoid foaming. Each component of the ABBOTT PRISM HTLV-I/HTLV-II Wash Kit should be at room temperature (15-30°C) and then mixed before loading onto the ABBOTT PRISM System.

### Table 3

<table>
<thead>
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<th>Centrifugation Time (minutes)</th>
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NOTE: Gently invert each component 3 times prior to loading on the ABBOTT PRISM System to ensure a homogenous solution. Additional gentle inversion may be required to thoroughly suspend microparticles. Avoid foaming. Each component of the ABBOTT PRISM HTLV-I/HTLV-II Wash Kit should be at room temperature (15-30°C) and then mixed before loading onto the ABBOTT PRISM System.
• Verify that all labeling symbols match the symbols on each reagent label. (Refer to the symbol key in the \textit{PRODUCT} section of this package insert, and the ambient reagent bay and refrigerator diagrams provided with the ABBOTT PRISM System.)

• Verify that all tubing is securely fastened to the corresponding wash and reagent bottles.

• Inspect the waste containers. Empty and clean as defined in the ABBOTT PRISM Operations Manual, Section 9, if necessary.

• Prepare Activator Solution (refer to the Preparation of Activator Solution section of this package insert) and load into the ABBOTT PRISM System.

• Verify adequate number of ABBOTT PRISM Reaction Trays are in the Tray Loader.

• Verify adequate number of ABBOTT PRISM Pipette Tips are in the Pipette Tip Rack.

• Perform the prime procedure (refer to the ABBOTT PRISM Operations Manual, Section 5).

1. Initiate sample processing. Open the bottles in the calibrator pack and place in the calibrator rack. Load the calibrator and sample racks, including the run controls. Refer to the QUALITY CONTROL PROCEDURES, Control Handling Procedure, under Controls in this package insert.

2. After the calibrators and positive assay controls have been automatically pipetted, remove the calibrator rack. Close the calibrator and positive assay control bottles and return them to 2-8°C storage.

• Each specimen is initially tested once, unless the operator overrides this automatic function of the ABBOTT PRISM System.

• Sample racks may be removed after the samples have been pipetted.

NOTE: No operator interaction is required for the following steps, which are automatically carried out by the ABBOTT PRISM System: reaction transport, calibrator/assay control/sample/release control pipetting, incubation, reagent dispense, sample reading, data reduction, run validity and result determination.

• After specimen processing is complete, perform the purge procedure. (Refer to the ABBOTT PRISM Operations Manual, Section 5.) Refer to the ABBOTT PRISM Operations Manual, Section 5, for a detailed description of CNHA procedures. The ABBOTT PRISM HTLV-I/HTLV-II assay is a three-step ChLIA procedure.

QUALITY CONTROL PROCEDURES

Calibration
The ABBOTT PRISM HTLV-I/HTLV-II Negative and Positive Calibrators and HTLV-II Positive Assay Control (1) are automatically tested in replicate at the beginning of each batch. The ABBOTT PRISM System will not generate results when calibrator Positive Assay Control (1) are automatically tested in triplicate at the beginning of each batch. The ABBOTT PRISM System will not generate results when calibrator/assay control/sample/release control pipetting, incubation, reagent dispense, sample reading, data reduction, run validity and result determination.

2. After specimen processing is complete, perform the purge procedure. (Refer to the ABBOTT PRISM Operations Manual, Section 5.) Refer to the ABBOTT PRISM Operations Manual, Section 5, for a detailed description of CNHA procedures. The ABBOTT PRISM HTLV-I/HTLV-II assay is a three-step ChLIA procedure.

Verification of Results
• In the ABBOTT PRISM HTLV-I/HTLV-II v assay, specimens with Net Counts less than the cutoff value are nonreactive and need not be tested further. Nonreactive specimens are considered negative for anti-HTLV-I/HTLV-II by the criteria of the ABBOTT PRISM HTLV-I/HTLV-II v assay.

• Specimens with Net Counts greater than or equal to the cutoff value are considered initially reactive by the criteria of the ABBOTT PRISM HTLV-I/HTLV-II v assay. All specimens (excluding non-frozen plasma/serum specimens) that are reactive on initial testing must be centrifuged prior to retesting according to the table in the \textit{SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS} section of this package insert. Initially reactive specimens must be retested in duplicate using the ABBOTT PRISM HTLV-I/HTLV-II v Assay Kit.

NOTE: Specimens released within 24 hours of initial centrifugation do not require reprocessing.

• If the sample Net Counts for both repeats are less than the cutoff value, the specimen is considered nonreactive. Reactive specimens are considered reactive for anti-HTLV-I/HTLV-II by the criteria of the ABBOTT PRISM HTLV-I/HTLV-II v assay.

• If the sample Net Counts for either duplicate repeat are greater than or equal to the cutoff value, the specimen is considered repeatedly reactive. Reactively reactive specimens are considered reactive for anti-HTLV-I/HTLV-II by the criteria of the ABBOTT PRISM HTLV-I/HTLV-II v assay.

Follow appropriate FDA recommendations and regulations for specimens found to be repeatedly reactive.

Individuals who are repeatedly reactive may be referred for medical evaluation and additional testing.

Reading Results
Some S/CO values may be flagged with ‘+’ or ‘−’ symbols. For more information on sample reports, refer to the ABBOTT PRISM Operations Manual, Section 5, Operating/Instructions, Reports. The ABBOTT PRISM System reports sample results in Net Counts and S/CO. Net Counts are used by the ABBOTT PRISM System to interpret results. The S/CO value is provided to the operator to show reactivity relative to the cutoff value. In the ABBOTT PRISM HTLV-I/HTLV-II v assay, specimens with S/CO values less than 1.00 are considered nonreactive. Specimens with an S/CO value of greater than or equal to 1.00 are considered reactive.

System Errors
For a description of the error codes that appear on ABBOTT PRISM System reports, refer to the ABBOTT PRISM Operations Manual, Section 10.

LIMITATIONS OF THE Procedure
• This assay was designed and validated for use with individual human serum and plasma specimens. This assay has not been validated for use with pooled specimens.

• The ABBOTT PRISM HTLV-I/HTLV-II v assay does not discriminate between HTLV-I and HTLV-II anti-HTLV-II antibodies.

• A test result that is negative does not exclude the possibility of exposure to or infection with HTLV-I and/or HTLV-II. Negative results in this assay in individuals with prior exposure to HTLV-I and/or HTLV-II may be due to antibody levels below the cutoff value, lack of antibody reactivity to the HTLV antigen used in this assay.
SPECIFIC PERFORMANCE CHARACTERISTICS

Assay Reproducibility

Assay reproducibility was determined by testing a seven-member panel consisting of three diluted specimens reactive or borderline reactive for anti-HTLV-I (panel members 1, 2, and 3); three diluted specimens reactive or borderline reactive for anti-HTLV-II (panel members 4, 5, and 6); and one specimen nonreactive for both anti-HTLV-I and anti-HTLV-II (panel member 7). Panel members were prepared in reconstituted human plasma. Each panel member was tested in replicates of four in five runs over five days with each of three reagent lots at five sites. In addition, each panel member was tested in replicates of four in five runs over five days with one of the three panel members as a subchannel. The Negative, Positive, and Supplemental Controls were tested at the beginning and end of each run on each subchannel. In three and one assay standard deviation (SD) and percent coefficient of variation (CV) were determined with a variance component analysis for a mixed model (Table IV).

Does not use specimens with obvious microbial contamination, gross lipemia, or gross hemolysis.

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Analysis, for a mixed model (Table III).

The Negative, Positive, and Supplemental Controls were automatically tested in triplicate at the beginning of each run on each subchannel. The intra-assay and inter-assay standard deviation (SD) and percent coefficient of variation (CV) were determined with a variance component analysis for a mixed model (Table IV).

As previously stated in the specific performance characteristics section of this package insert for assay performance characteristics.

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BIBLIOGRAPHY


6E50-01-68_Eng_ReIn.indd   8