HUMAN IMMUNODEFICIENCY VIRUS TYPES 1 AND 2:
(E. COLI, B. MEGATERIUM, RECOMBINANT ANTIGEN)

HIVAB™ HIV-1/HIV-2 (rDNA) EIA

NAME AND INTENDED USE

HIVAB HIV-1/HIV-2 (rDNA) EIA IS AN IN VITRO ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUSES TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM, PLASMA, OR CADAVERIC SERUM.

WARNING: A SOFTWARE UPGRADE AND/OR PROTOCOL EDITS MAY BE REQUIRED PRIOR TO IMPLEMENTING THIS ASSAY. PLEASE CONTACT YOUR LOCAL CUSTOMER SUPPORT CENTER.
Epidemiologic data suggest that the Acquired Immunodeficiency Syndrome (AIDS) is caused by at least two types of human immunodeficiency viruses, collectively designated human immunodeficiency virus (HIV). More than 100,000 cases of AIDS have now been isolated from patients with AIDS and HIV-related complex (ARC), and from healthy persons estimated to have been infected. The virus is highly contagious and can be transmitted by exposure to blood or blood products; or from an infected mother to her fetus or child. The prevalence of HIV antibody in AIDS and ARC patients and persons at risk is high and the virus can be isolated from nearly 90% of all seropositive individuals.1

In 1982, a second virus, HIV-2, was isolated from patients with AIDS in West Africa. HIV-1 and HIV-2 viruses have also been identified in:

1. Europe, the U.S., and other areas where homosexual relations with individuals from this region occurred,
2. Homosexual patients in homosexual areas or areas of the world with high sex between men, and
3. Cases of HIV-1 infection reported in the United States.1

A critical test in the diagnosis of AIDS includes an examination of the patient's immune status and a clinical history. In order to provide maximum protection of the blood supply, enzyme immunoassays were inactivated microorganisms will not transmit infection. Therefore, all human components. Some components sourced from human blood have been

CAUTION: This product contains human sera and/or cells. These may be infectious. If such material is inhaled or swallowed, use a cotton dust mask and wash with soap and warm water.

NAME AND INTENDED USE

The HIVAB HIV-1/HIV-2 (rDNA) EIA is an in vitro enzyme immunoassay for the qualitative detection of antibodies to human immunodeficiency virus type 1 and/or type 2 (HIV-1, HIV-2) in human serum, plasma or cadaveric serum.

SUMMARY AND EXPLANATION OF THE TEST

HIV-1/HIV-2 antibodies are detected by an enzyme immunoassay utilizing recombinant antigens and polystyrene beads coated with horseradish peroxidase. This enzyme immunoassay is performed on a spectrophotometer.

HIVAB HIV-1/HIV-2 (rDNA) EIA does not discriminate between HIV-1 and HIV-2 reactive specimens. However, inactivated microorganisms will not transmit infection. Therefore, all human components. Some components sourced from human blood have been

HIV-1 antibody-containing sera have not been effective in altering the course of HIV-1 infection. Retrovirologically, the antibodies produced are directed against structural proteins and do not protect against reinfection with HIV. Therefore, it is important to note that the use of prophylactic and therapeutic agents. These precautions include, but are not limited to the following:

4. Clean and disinfect all spills of specimens or reagents using a 10% Sodium Hypochlorite solution or 10% Hydrogen Peroxide.

5. Decontaminate and dispose of all specimens, reagents and other potentially contaminated materials in accordance with local, state, and federal regulations.

CAUTION: This product contains human sera and/or cells. These may be infectious. If such material is inhaled or swallowed, use a cotton dust mask and wash with soap and warm water.

For Informational Use Only. Not to be used for performance assay. Refer to most current package insert accompanying kit.

REAGENTS

HIVAB HIV-1/HIV-2 (rDNA) EIA, 100/1000/5000 Tests

2 Vials (0.65 mL each)/3 Vials (5 mL each)/15 Vials (5 mL each) HIV-1 Antibody Positive Control (Mouse Monoclonal). Contains 10% Bovine Serum Proteins. Preservatives: Gentamicin Sulfate 0.01%, Sodium Azide 0.02%.

1 Vial (15 mL)/3 Vials (50 mL each)/9 Vials (50 mL each) Conjugate Diluent. Contains 10% Bovine Serum Proteins. Preservatives: Sodium Azide 0.1%, Gentamicin Sulfate 0.01%.

1 Bottle (3 mL)/3 Bottles (3 mL each)/15 Bottles (3 mL each) HIV-1 Positive Control (Mouse Monoclonal) Contains 10% Bovine Serum Proteins. Preservatives: Gentamicin Sulfate 0.05%, Sodium Azide 0.02%.

1 Bottle (10 tablets)/3 Bottles (4 tablets each)/10 Bottles (4 tablets each) POD (pH 5.0) Tablets. OPD/Tablet: 12.8 mg.

1 Bottle (20 mL)/3 Bottles (60 mL each)/15 Bottles (60 mL each) Peroxide.

There is no component B.

The Shipping Requirements must be met under the following conditions:

1. All Vials of HIVAB HIV-1/HIV-2 (rDNA) EIA and of any reagents used in this assay should be made in the United States and labeled according to United States Code Title 21, Part 210.

2. All Vials of HIVAB HIV-1/HIV-2 (rDNA) EIA and of any reagents used in this assay should be made in the United States and labeled according to United States Code Title 21, Part 210.

One of the following conditions must be met:

a. Either all Vials of HIVAB HIV-1/HIV-2 (rDNA) EIA and of any reagents used in this assay should be made in the United States and labeled according to United States Code Title 21, Part 210.

b. All Vials of HIVAB HIV-1/HIV-2 (rDNA) EIA and of any reagents used in this assay should be made in the United States and labeled according to United States Code Title 21, Part 210.

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A critical test in the diagnosis of AIDS includes an examination of the patient's immune status and a clinical history. In order to provide maximum protection of the blood supply, enzyme immunoassays were
**PROCEDURE**

1. Conjugate Concentrate and Conjugate Diluent should be brought to room temperature before use.
2. Transfer into a suitable container 5 mL of Diluent for OPD for each tablet to be dissolved.
3. Swirl container gently to obtain a homogeneous solution, remove and replace lid several times, and rinse dispenser to remove any air. The OPD Substrate Solution MUST BE DISPOSED WITHIN 60 MINUTES OF PREPARATION AND MUST NOT BE STORED.
4. Do not expose OPD reagents to strong light during storage or incubation.
5. Do not mix reagents from different lots.
6. If the desiccant obstructs the flow of beads, remove from bead bottle prior to dispensing beads. Replace desiccant in bottle and tightly cap bottle for storage. Do not store beads with dispenser attached to bottle.
7. Use a clean dedicated dispenser for the diluted conjugate to avoid contamination.
8. Diluent. This can be done most efficiently by slowly squeezing the small vial 2 to 3 times in an up-and-down motion. The OPD Substrate Solution MUST BE DISPOSED WITHIN 60 MINUTES OF PREPARATION AND MUST NOT BE STORED.
9. Serum, plasma, or cadaveric serum specimens with obvious microbial contamination must be repeated.
10. An absorbance value of less than 0.500 for either HIV-1 Positive Control replicate and/or specimen as well as for each substrate blank. Such runs indicate technique errors or deterioration of the kit reagents or OPD reagents. Such runs must be repeated.

**INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS**

The OPD Substrate Solution (OPD plus Diluent for OPD) should be colorless to pale yellow. A purple-red-orange color indicates that the reagent has been contaminated and must be discarded. An absorbance value of less than 0.500 for either HIV-1 Positive Control replicate and/or an absorbance value of less than 0.500 for either HIV-1 Negative Control replicate may indicate technique errors or deterioration of the kit reagents or OPD reagents. Such runs must be repeated.

**STORAGE INSTRUCTIONS**

1. Store kit magnets at 2 to 8°C. OPD Tablets and 1 N Sulfuric Acid must be stored at 2 to 8°C.
2. Bring all reagents to room temperature (15 to 30°C) for use and return them to storage conditions immediately after use.
3. Reseal the large vial. Mix thoroughly by slowly inverting the vial several times. Do not vortex.
4. The OPD Substrate Solution MUST BE DISPOSED WITHIN 60 MINUTES OF PREPARATION AND MUST NOT BE STORED.
5. Replace desiccant in bottle and tightly cap bottle for storage.
6. The Negative and HIV-1 Positive Controls, and the HIV-2 Positive Control, as provided, should be treated the same way as specimens.
7. Remove the date of dilution in the space provided on the Conjugate Diluent label.
8. All OPD reagent lots or 1 N Sulfuric Acid may be used with any Abbott EIA kit.
9. If serum, plasma, or cadaveric serum specimens are to be shipped, they may be stored at 2 to 8°C for a maximum of 14 days. For long-term storage, the specimens should be stored frozen. Samples have been tested after three freeze/thaw cycles and no performance difference was seen.

**REAGENTS**

Some components of this product contain Sodium Azide. For a specific listing, refer to the REAGENTS section of this package insert. The components containing Sodium Azide are classified per applicable European Community (EC) Directive as: Harmful (H). The following are the appropriate Risk (R) and Safety (S) phrases.

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<tr>
<td>R22 Harmful if swallowed.</td>
<td>S35 This material and its container must be disposed of in a safe way.</td>
</tr>
<tr>
<td>R26 Harmful if inhaled.</td>
<td>S37 Wear suitable protective clothing.</td>
</tr>
<tr>
<td>R36 Irritating to eyes.</td>
<td>S43 Avoid release to the environment. Refer to specific instruction safety data sheets.</td>
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<tr>
<td>R36 Irritating to the skin.</td>
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**Directives as: Harmful (Xn) and Dangerous for the environment (N).** The following are the appropriate Risk (R) and Safety (S) phrases.

- **R32 Contact with acids liberates very toxic gas.**
- **R22 Harmful if swallowed.**
- **R36 Irritating to eyes.**
- **R20 Harmful in contact with skin.**
- **R36 Irritating to the skin.**
- **R22 Harmful if swallowed.**
- **R36 Irritating to the skin.**
- **R32 Contact with acids liberates very toxic gas.**
- **S22 Do not allow to contact with skin.**
- **S25 Store in a well-ventilated area.**
- **S24 Avoid release to the environment.**
- **S36 Wear suitable protective clothing.**
- **S45 Avoid release to the environment.**
- **S53 No special precautions required.**
- **S37 Wear suitable protective clothing.**
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- **S53 No special precautions required.**

**Handling Precautions**

1. Do not use past the expiration date.
2. Do not mix reagents from different lots.

**NOTE:** All OPD reagent lot or 1 N Sulfuric Acid lot may be used with any Abbott EIA kit.

**Avoid microbial contamination of reagents when removing aliquots from the reagent vials. Use of disposable pipette tips is recommended.**

**Do not expose OPD reagents to strong light during storage or incubation.**

**Avoid contact of the OPD Substrate Solution or 1 N Sulfuric Acid with any oxidizing agent.**

**Do not allow OPD Substrate Solution to come in contact with any metal parts.**

**Prior to use, three glassware pieces to be used for OPD Substrate Solution thoroughly with 1 N Sulfuric Acid (if applicable) using shaking approximately 10% of the container volume followed by three washes of distilled water of the same volume.**

**If the desiccant obstructs the flow of beads, remove from bead bottle prior to dispensing beads. Replace desiccant in bottle and tightly cap bottle for storage. Do not store beads with dispenser attached to bottle.**

**Use a clean dedicated dispenser for the diluted conjugate to avoid contamination.**

**CAUTION:** Do not open OPD Tablet bottle until it is at room temperature. At least 5 minutes, but no more than 10 minutes prior to Color Development, remove the OPD Substrate Solution by dispensing the OPD Substrate Solution into the Color Development tray. For use, Do NOT USE A TABLET THAT IS NOT INTACT.

Using clean pipettes and metal-free containers (such as plastic pipette or acid-washed and labelled water-washed glassware) follow the procedure below.

1. Transfer into a suitable container 5 mL of Diluent for OPD for each tablet to be dissolved.
2. Transfer an appropriate number of OPD Tablets (see OPD Preparation Chart) into a measured amount of Diluent for OPD using a nonmetallic or nonplastic dispenser. Remove desiccant from bottle immediately. A need to remove a tablet and dispenser will vary. Allow warming to dissolve. Do not cap or stopper the OPD Tablet bottle prior to or during dissolution.
3. If serum, plasma, or cadaveric serum specimens are to be shipped, they may be stored at 2 to 8°C for a maximum of 14 days. For long-term storage, the specimens should be stored frozen. Samples have been tested after three freeze/thaw cycles and no performance difference was seen.
4. The Negative and HIV-1 Positive Controls, and the HIV-2 Positive Control, as provided, should be treated the same way as specimens.
5. Remove the date of dilution in the space provided on the Conjugate Diluent label.
6. All OPD reagent lots or 1 N Sulfuric Acid may be used with any Abbott EIA kit.
7. If serum, plasma, or cadaveric serum specimens are to be stored, they may be stored at 2 to 8°C for a maximum of 5 days. For long-term storage, the specimens should be stored frozen. Samples have been tested after three freeze/thaw cycles and no performance difference was seen.
8. If serum, plasma, or cadaveric serum specimens are to be shipped, they may be stored at 2 to 8°C for a maximum of 14 days. For long-term storage, the specimens should be stored frozen. Samples have been tested after three freeze/thaw cycles and no performance difference was seen.
9. Serum or plasma, or cadaveric serum specimens to be used for the horizontal test are packed in a cool box containing certified ice packs.
10. Serum, plasma, or cadaveric serum specimens containing hazardous materials may give insufficient test results. Such specimens should be clarified prior to testing.

**PROCEDURE**

1. Do not use any reagents which are frozen. Sulfuric Acid with any oxidizing agent. Do not allow OPD Substrate Solution to come in contact with any metal parts. OPD Substrate Solution. Do not expose OPD reagents to strong light during storage or incubation.
2. Do not mix reagents from different lots.
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HIVAB HIV-1/HIV-2 (rDNA) EIA TEST PROCEDURE

Materials Required but not Provided
- Precipitate plates or similar equipment to deliver 50 µL, 150 µL, 200 µL, 300 µL (precision ± 1%, 1 mL, precision ± 1%)-
- Quartz fluorimeter or device for measuring absorbance with a cuvette and a double-beam.
- Pipettes or devices to dispense beads with a vacuum source and a double trap for removing air and preventing maximum pressure of O(2) delivery in each well of 100 µL per well.
- COMMANDER Dynamic Incubator (DI)
- Disposable, graduated pipettes or dispenser for dispensing OPD for PID.
- Nonmetallic forceps.
- COMMANDER Operations Manual(s) and note special COMMANDER instructions below.
- QwikWash®; or device for washing beads with a vacuum source and a double trap for removing air and preventing maximum pressure of O(2) delivery in each well of 100 µL per well.
- COMMANDER Dynamic Incubator (DI).
- Abbott OPD (o-Phenylenediamine • 2 HCl) Reagent, No. 6172.

Materials Required but not Provided
- COMMANDER Operations Manual(s) and note special COMMANDER instructions below.
- Abbott OPD (o-Phenylenediamine • 2 HCl) Reagent, No. 6172.
- COMMANDER Dynamic Incubator (DI).

Preliminary Comments
1. Assay three Negative and two HIV-1 Positive Controls, and two HIV-2 Positive Controls. (rDNA) EIA. When configuring the Assay Protocols in the FPC, ensure the Assay Procedure is compatible with this assay. Follow manufacturer's directions to achieve the appropriate band width of 10 nm ± 2 nm.

CAUTION: Verify that all assay protocols are configured correctly in the software for List Number 3A77 without editing. Verify that all other assay protocol parameters match the Abbott provided assay protocol parameters. The following FIRST INCUBATION and SECOND INCUBATION instructions should be used when processing assays on the QUANTUM II, the ROTATION incubation method while inserting and removing trays of the same batch. Select the incubation temperature and time(s) designated in the ASSAY PROCEDURE section which follows.

CAUTION: Failure to use the Dynamic Incubator for incubation in the manner described in the Dynamic Incubator Operations Manual may result in incorrect assay results. When inserting the tray into the FPC at the conjugate addition step, the strip guide should be adjusted to the appropriate conjugate level. Note: For operation of the Quanta II and Spectrophotometer, refer to the manual for your specific instrument.

PROCEDURAL NOTES

Sample Pipetting and Dilution
1. When using a manual method of sample dilution follow the instructions in the ASSAY PROCEDURE.

2. If using Flexible Pipetting Center (FPC™) the Specimen Diluent must be dispensed using the Bottle (0102) diluter.

3. Prior to beginning the assay procedure, bring all reagents to room temperature (15 to 30°C) and mix gently.

4. Do not allow acid or OPD Substrate Solution to contact metal.

5. If there is an interruption during the reading of samples, reblank the instrument and reinsert the assay tray.

6. To determine the absorbance of the substrate blank must be made. The absorbance value of the substrate blank, as measured by the second incubation, must be less than or equal to 0.200. If the absorbance value of the substrate blank is not valid, repeat steps 3 and 4 using the alternate substrate blank.

ASSAY PROCEDURE (See Preliminary Comments and Procedural Notes)

ASSAY SELECTION ON THE PPC
1. Insert tray and select the appropriate assay number for the HIVAB HIV-1/HIV-2 (rDNA) EIA.

2. Filter-aided lines are consistent with the assay package insert specifications and are supported by documentation at the time of use. Follow the instructions in the instrument manual.

3. When dispensing both acid and OPD Substrate Solution, the order of dispensing must be OPD Substrate Solution first, followed by acid. Ensure that the Dynamic Incubator is compatible with this assay. Follow manufacturer's directions to achieve the appropriate band width of 10 nm ± 2 nm.

ASSAY SELECTION ON THE PPC
1. Insert tray and select the appropriate assay number for the HIVAB HIV-1/HIV-2 (rDNA) EIA.

2. When dispensing both acid and OPD Substrate Solution, the order of dispensing must be OPD Substrate Solution first, followed by acid. Ensure that the Dynamic Incubator is compatible with this assay. Follow manufacturer's directions to achieve the appropriate band width of 10 nm ± 2 nm.

3. BLANKING (PPC only)

4. When the conjugate incubation step, prepare a blanks tray using a separate tray. Place one blanking bead for each of the five wells. All through 4.2. If the construction of the conjugate and OPD Substrate Solution, insert the blanks tray, followed immediately by the first assay tray.

5. Remove and discard cover seal. Wash each bead.

6. After each step, visually verify the presence of solution and bead in each well.

7. When washing beads, remove cap from bead bottle, attach Bead Dispenser and dispense beads into wells of the reaction tray as directed in the Bead Dispenser manual.

8. Add 200 µL of diluted conjugate to each reaction well.

9. In the Pipetting Section for the PCN2, change the Component Location to Bead Dispenser.

10. In the General Information section change the Analyzer Test Number to 71.

11. Remove and discard cover seal. Wash each bead.

12. If using the QwikWash®, wash each bead gently for 10 sec.

13. CAUTION: Failure to use the Dynamic Incubator for incubation in the manner described in the Dynamic Incubator Operations Manual may result in incorrect assay results.

14. When inserting the tray into the FPC at the conjugate addition step, the strip guide should be adjusted to the appropriate conjugate level.

CAUTION: Verify that all assay protocols are configured correctly in the software for List Number 3A77 without editing. Verify that all other assay protocol parameters match the Abbott provided assay protocol parameters. The following FIRST INCUBATION and SECOND INCUBATION instructions should be used when processing assays on the QUANTUM II, the ROTATION incubation method while inserting and removing trays of the same batch. Select the incubation temperature and time(s) designated in the ASSAY PROCEDURE section which follows.

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Color Development (QUANTUM II and SPECTROPHOTOMETER)
1. When transferring beads from wells to assay tubes, align inverted covers of tubes over their respective wells in the reaction tray. Press the tubes tightly over the wells and insert tray and tubes together so that beads fall into corresponding tubes. Blot excess water from top of tube cap.

2. Add strong light during Color Development.

3. Do not allow acid or OPD Substrate Solution to contact metal.

4. When dispensing both acid and OPD Substrate Solution, the order of dispensing must be OPD Substrate Solution first, followed by acid. Ensure that the Dynamic Incubator is compatible with this assay. Follow manufacturer's directions to achieve the appropriate band width of 10 nm ± 2 nm.

ASSAY SELECTION ON THE PPC
1. Insert tray and select the appropriate assay number for the HIVAB HIV-1/HIV-2 (rDNA) EIA.

2. When dispensing both acid and OPD Substrate Solution, the order of dispensing must be OPD Substrate Solution first, followed by acid. Ensure that the Dynamic Incubator is compatible with this assay. Follow manufacturer's directions to achieve the appropriate band width of 10 nm ± 2 nm.

3. BLANKING (PPC only)

4. When the conjugate incubation step, prepare a blanks tray using a separate tray. Place one blanking bead for each of the five wells. All through 4.2. If the construction of the conjugate and OPD Substrate Solution, insert the blanks tray, followed immediately by the first assay tray.

5. Remove and discard cover seal. Wash each bead.

6. After each step, visually verify the presence of solution and bead in each well.

7. When washing beads, remove cap from bead bottle, attach Bead Dispenser and dispense beads into wells of the reaction tray as directed in the Bead Dispenser manual.

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COLOR DEVELOPMENT (QUANTUM II and SPECTROPHOTOMETER)
13. Immediately transfer tubes to assay tubes.
14. Prime DPO Dispenser immediately prior to dispensing DPO Substrate Solution. Assign the appropriate assay procedure code configured on the FPC.

PREPARATION OF THE WATER TUBE
17. Pipette approximately 2 mL of destilled or deionized water into an empty tube.

READING QUANTUM II and SPECTROPHOTOMETER
18. In Mode 5, blank the instrument with the water tube. (See appropriate Operations Manual for running Mode 5).
19. Determine the absorbance of the substrate blank. The substrate blank must be greater than or equal to 0.050 and less than or equal to 0.085. Stop the Mode 5 assay.
20. Select mode for processing: Hydro HIV-II (DNA) EIA.
21. Blank the instrument with the valid substrate blank.
22. Determine absorbance of Controls and specimens (within 2 hours after addition of substrate blank).

QUALITY CONTROL PROCEDURES
1. Substrate Blank Acceptance Criteria
   a. Quantum II Users: Acceptance criteria are met when the absorbance is an average of three replicate substrate blanks that is equal to or greater than 0.050 and less than or equal to 0.085. If the absorbance is not within the acceptable range, the test must be repeated.
   b. COMMANDER users: Acceptance criteria are met when the absorbance is an average of three replicate substrate blanks that is equal to or greater than 0.050 and less than or equal to 0.085. If the absorbance is not within the acceptable range, the test must be repeated.

2. Control Calculations and Acceptance Criteria
   a. HIV-1 Positive Control: The absorbance is determined by relating the absorbance of the specimen to the Cutoff Value.
   b. HIV-2 Positive Control: The absorbance is determined by relating the absorbance of the specimen to the Cutoff Value.
   c. Negative Control: The absorbance is determined by relating the absorbance of the specimen to the Cutoff Value.

For Informational Use ONLY. Not to be used for performing assay. Refer to most current package incorporating kit.

MN SAMPLE REACTIVITY MY5

MIN SAMP REACT \[ \text{ (ppm - GC \( \leq \))} \]

POSITIVE CONTROLS

Example:

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MN SAMPLE REACTIVITY MY5

MIN SAMP REACT \[ \text{ (ppm - GC \( \leq \))} \]

POSITIVE CONTROLS

Example:

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<td>3</td>
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</tr>
</tbody>
</table>
INTERPRETATION OF RESULTS

1. Specimens with absorbance values less than or equal to the Cutoff Value are considered not reactive, and may be considered negative for antibodies to HIV-1 and HIV-2.

2. Specimens with absorbance values greater than or equal to the Cutoff Value are considered initially reactive and should be released in duplicate before interpretation using the original sample.

3. If a positive result is obtained using duplicate reactions, the specimen is considered reactive (positive).

4. If the absorbance value is less than the cutoff when retested, the specimen may be considered negative for antibodies to HIV-1 and HIV-2. Further testing is not required.

5. Specimens found to be repeatedly reactive by the HIVAB HIV-1/HIV-2 (rDNA) EIA reactivity test have specific supplemental testing. It was also found to be reactive with these tests, the specimen is considered positive for antibodies to HIV-1 and HIV-2.

6. The interpretation of results of specimens found to be repeatedly reactive by the HIVAB HIV-1/HIV-2 (rDNA) EIA is the same as the interpretation of repeat reactive specimens with high absorbance on EIA.

LIMITATIONS OF THE PROCEDURE

The HIVAB HIV-1/HIV-2 (rDNA) EIA procedure and the Interpretation of Results must be followed closely when testing for the presence of antibodies to HIV in plasma, serum, or cadaveric serum from individual subjects. Because the EIA was designed to test individual units of plasma or serum, most data regarding interpretation were derived from testing individual serum samples. Insufficient data are available to interpret tests performed on other body fluids, pooled plasma or products, and products made from such pooled testing of these specimens is not recommended.

HIVAB HIV-1/HIV-2 (rDNA) EIA detects antibodies to HIV-1 and HIV-2 in blood and there is useful in screening blood and plasma donated by multitransfused and further reduced by contact with subsequent blood donors. The sensitivity and specificity of this test are far higher than needed to screen for HIV antibodies.

The reactivity of HIV-infected patients with known antibodies to HIV-1 indicates the presence of antibodies to HIV-2. It is recommended that reactive specimens be investigated by an additional more specific, or confirmatory test. A patient with known antibodies to HIV-1 is considered HIV-2 positive by the criteria of the HIVAB HIV-1/HIV-2 (rDNA) EIA.

The results of testing specimens from random blood donors for antibodies to HIV-1 and HIV-2 are shown in Table I.

Sensitivity and Specificity

The assay was tested on known sera and plasma samples from HIV-infected individuals. The results of testing these specimens showed that the assay was 100% sensitive and specific.

The reactivity of HIV-infected patients with known antibodies to HIV-1 indicates the presence of antibodies to HIV-2. It is recommended that reactive specimens be investigated by an additional more specific, or confirmatory test.
TABLE III
Detection of Antibodies to HIV-1 and/or HIV-2 in Seropositive Samples

<table>
<thead>
<tr>
<th>Group</th>
<th>Number Tested</th>
<th>Reactive</th>
<th>Repeatedly Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV+</td>
<td>100</td>
<td>100.00</td>
<td>100.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>50</td>
<td>50.00</td>
<td>50.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>20</td>
<td>20.00</td>
<td>20.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>10</td>
<td>10.00</td>
<td>10.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>5</td>
<td>5.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Total: 100% (150/150) 150 (100%) 0 (0.0%)

Note: All samples were reactive in the reagent lot used.

TABLE IV
Detection of Reactivities of Seropositive Individuals in Western Blot

<table>
<thead>
<tr>
<th>Number Tested</th>
<th>Reactive</th>
<th>Repeatedly Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV+</td>
<td>20</td>
<td>20.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>10</td>
<td>10.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>5</td>
<td>5.00</td>
</tr>
</tbody>
</table>

Total: 100% (45/45) 45 (100%) 0 (0.0%)

Note: All samples were reactive in the reagent lot used.

TABLE V
Detection of Antibodies to HIV-1 in Individuals at High Risk for HIV Infection

<table>
<thead>
<tr>
<th>Number Tested</th>
<th>Reactive</th>
<th>Repeatedly Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV+</td>
<td>50</td>
<td>50.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>25</td>
<td>25.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>10</td>
<td>10.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>5</td>
<td>5.00</td>
</tr>
</tbody>
</table>

Total: 100% (100/100) 100 (100%) 0 (0.0%)

Note: All samples were reactive in the reagent lot used.

TABLE VI
Detection of Antibodies to HIV-1 in Unselected Specimens from an HIV-2 Endemic Area

<table>
<thead>
<tr>
<th>Number Tested</th>
<th>Reactive</th>
<th>Repeatedly Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV+</td>
<td>100</td>
<td>100.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>50</td>
<td>50.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>20</td>
<td>20.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>10</td>
<td>10.00</td>
</tr>
<tr>
<td>HIV+</td>
<td>5</td>
<td>5.00</td>
</tr>
</tbody>
</table>

Total: 100% (200/200) 200 (100%) 0 (0.0%)

Note: All samples were reactive in the reagent lot used.

TABLE VII
Performance of the HIVAB HIV-1/HIV-2 (rDNA) EIA on Serocoverting Sera

<table>
<thead>
<tr>
<th>Donor (No.)</th>
<th>Days of Postmortem</th>
<th>HIVAB HIV-1/HIV-2 (rDNA) EIA</th>
<th>Western Blot Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>121</td>
<td>1</td>
<td>HIV+</td>
<td>HIV+</td>
</tr>
<tr>
<td>122</td>
<td>2</td>
<td>HIV+</td>
<td>HIV+</td>
</tr>
<tr>
<td>123</td>
<td>3</td>
<td>HIV+</td>
<td>HIV+</td>
</tr>
<tr>
<td>124</td>
<td>4</td>
<td>HIV+</td>
<td>HIV+</td>
</tr>
<tr>
<td>125</td>
<td>5</td>
<td>HIV+</td>
<td>HIV+</td>
</tr>
<tr>
<td>126</td>
<td>6</td>
<td>HIV+</td>
<td>HIV+</td>
</tr>
<tr>
<td>127</td>
<td>7</td>
<td>HIV+</td>
<td>HIV+</td>
</tr>
</tbody>
</table>

Note: All samples were reactive in the reagent lot used.

** Special Note: ALL samples were reactive in both tests.

All samples were reactive in the reagent lot used.

Note: All samples were reactive in the reagent lot used.

TABLE VIII
Reactivity with HIVAB HIV-1/HIV-2 (rDNA) EIA

<table>
<thead>
<tr>
<th>Population</th>
<th>No. of Specimens</th>
<th>Mean S/CO Ratio</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV+</td>
<td>100</td>
<td>100.00</td>
<td>10.0%</td>
</tr>
<tr>
<td>HIV+</td>
<td>50</td>
<td>50.00</td>
<td>5.0%</td>
</tr>
<tr>
<td>HIV+</td>
<td>20</td>
<td>20.00</td>
<td>2.0%</td>
</tr>
<tr>
<td>HIV+</td>
<td>10</td>
<td>10.00</td>
<td>1.0%</td>
</tr>
<tr>
<td>HIV+</td>
<td>5</td>
<td>5.00</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Total: 100% (150/150) 150 (100%) 0 (0.0%)

Note: All samples were reactive in the reagent lot used.

** Special Note: ALL samples were reactive in both tests.

All samples were reactive in the reagent lot used.

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TABLE VIII
Reactivity with HIVAB HIV-1/HIV-2 (rDNA) EIA

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Total: 100% (150/150) 150 (100%) 0 (0.0%)

Note: All samples were reactive in the reagent lot used.

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<tbody>
<tr>
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<td>50</td>
<td>150</td>
<td>4.140</td>
</tr>
<tr>
<td>Normal Donor</td>
<td>50</td>
<td>150</td>
<td>4.075</td>
</tr>
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<td>Postmortem Combined</td>
<td>150</td>
<td>300</td>
<td>3.901</td>
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<tr>
<td>Normal Donor Combined</td>
<td>150</td>
<td>300</td>
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