

HIV 1/2 STAT-PAK® ASSAY

Read this Product Insert completely before using the product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate Test Results. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens.¹

CLIA Complexity: WAIVED FOR FINGERSTICK WHOLE BLOOD AND VENIPUNCTURE WHOLE BLOOD. ANY MODIFICATION BY THE LABORATORY TO THE TEST SYSTEM OR FDA APPROVED TEST SYSTEM INSTRUCTIONS WILL RESULT IN THE TEST NO LONGER MEETING THE REQUIREMENTS FOR WAIVED CATEGORY.

CLIA Complexity: MODERATE FOR SERUM AND PLASMA SAMPLES

STORAGE: Store at 8 to 30°C (46 to 86°F)

NAME AND INTENDED USE

The Chembio HIV 1/2 STAT-PAK® Assay is a single-use immunochromatographic test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Chembio HIV 1/2 STAT-PAK® assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.

RESTRICTIONS

- Sale of the Chembio HIV 1/2 STAT-PAK® Assay is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities that provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.
- The Chembio HIV 1/2 STAT-PAK® Assay is approved for use only by an agent of a clinical laboratory.
- Non-clinical testing sites that offer waived rapid HIV tests must either have their own CLIA Certificate of Waiver or have an agreement to work under the CLIA Certificate of an existing laboratory.
- Test subjects must receive the "Subject Information Notice" prior to specimen collection and appropriate information when test results are provided.
- The Chembio HIV 1/2 STAT-PAK® Assay is not approved for use to screen blood, plasma, cell or tissue donors.

SUMMARY AND EXPLANATION OF THE TEST

Discovered in 1983, the Human Immunodeficiency Virus is a retrovirus and identified as the etiologic agent for the Acquired Immunodeficiency Syndrome (AIDS), and AIDS related complex.² AIDS is characterized by changes in the population of T-cell lymphocytes that play a key role in the immune defense system. In the infected individual the virus causes a depletion of a subpopulation of T-cells, called T-helper cells, which leaves these patients susceptible

to opportunistic infections and certain malignancies. The major routes of transmission are sexual contact, exposure to contaminated blood or blood products (including sharing of contaminated syringes and needles) and mother-to-newborn transmission.³⁻⁵

Although there has been a decrease in the rate of infection in certain countries, the number of persons infected with HIV globally has continued to increase. By the end of 2005 there were approximately 40.3 million people living with HIV/AIDS, an increase from nearly 37.5 million in 2003. An estimated 5 million people were newly infected with HIV in 2005. In the same year more than 3 million died of AIDS-related illness; more than 500,000 of these were children.⁶

HIV infection, AIDS and AIDS related complex have become a leading cause of illness and death in the United States for the past two decades. As of December 2001, a total of 774,467 persons were reported with AIDS and 448,060 of these persons had died. Approximately 800,000 – 900,000 persons in the United States are infected with HIV and approximately 80,000 - 280,000 of these persons may not be aware of their infected status.⁷

The HIV virus consists of a genomic RNA molecule protected by a capsid and an envelope. The HIV envelope is the major target for a humoral antibody response. The presence of the virus in patients causes the immune system to elicit the production of antibodies. The detection of these antibodies can be used as a diagnostic tool.

Enzyme Immunoassays (EIAs), Western Blots (WB), Nucleic Amplification Test (NAT) assay and various other test systems are currently available for detection of HIV-1 and HIV-2 infection.⁸⁻¹² The Chembio HIV 1/2 STAT-PAK[®] Assay utilizes immobilized antigens for the detection of antibodies to HIV-1 and HIV-2, and is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

BIOLOGICAL PRINCIPLES OF THE TEST

The Chembio HIV 1/2 STAT-PAK[®] Assay employs a unique combination of a specific antibody binding protein which is conjugated to colloidal gold dye particles and HIV-1/2 antigens which are bound to the solid phase membrane. The venous or capillary (fingerstick) whole blood, serum or plasma is applied to the SAMPLE (S) well of test device followed by the addition of Running Buffer. The Buffer facilitates the lateral flow of the specimen and test reagents and promotes the binding of the antibodies to the antigen. The specimen/buffer mixture migrates along the test strip by capillary action, reconstituting the conjugate. If present, the antibodies bind to the colloidal gold conjugated antibody binding protein. In a reactive sample, the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST (T) area producing a pink/purple line. In the absence of HIV-1 and HIV-2 antibodies, there is no pink/purple line in the TEST (T) area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL (C) area containing immunoglobulin G antigens. This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device.

MATERIALS PROVIDED

- Each Kit contains the components to perform 20 tests:
 - 20 STAT-PAK[®] Individually Pouched Test Devices
 - 20 Copies of Subject Information Notice
 - 20 Disposable 5µL Sample Loops
 - 1 HIV Running Buffer (3.5mL)
 - 1 Product Insert for the Chembio HIV 1/2 STAT-PAK[®] Assay

MATERIALS REQUIRED AND AVAILABLE AS AN ACCESSORY TO THE KIT

Chembio HIV Reactive/Nonreactive Controls (Catalog # 60-9549-0).

Each package contains:

- 1 HIV 1 Reactive Control (0.25mL)
- 1 HIV 2 Reactive Control (0.25mL)
- 1 Nonreactive Control (0.25mL)
- 1 Product Insert for the Chembio HIV Reactive/Nonreactive Controls

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, watch, or other timing device
- Pipettor capable of delivering 5µL of sample may be used in lieu of the disposable 5µL sample loop supplied with the Kit (for other than fingerstick whole blood specimens)
- Disposable gloves
- Sterile gauze (for fingerstick whole blood specimens)
- Antiseptic wipes
- Biohazard disposal container
- Sterile Safety Lancet (for fingerstick whole blood specimens)
- Collection devices for specimens (other than fingerstick whole blood specimens)

WARNINGS

For *IN VITRO* diagnostic use

1. Read the Product Insert completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
2. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens.¹
3. Use of this test Kit with specimen types other than those specifically approved for use with this device may result in inaccurate test results.
4. This test is CLIA-waived for use only with fingerstick whole blood and venipuncture whole blood samples.
5. This test should be performed at 18 to 30°C (64 to 86°F). If stored refrigerated, ensure that the pouch is brought to operating temperature before performing testing.
6. If the test Kit is stored at temperatures outside the storage temperature 8 to 30°C (46 to 86°F), or used outside the operating temperature 18 to 30°C (64 to 86°F), use the Kit Controls to ensure proper performance of the test.
7. Individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce false negative results.

PRECAUTIONS

Safety Precautions

1. Handle the specimens and materials contacting specimens as if capable of transmitting infection.
2. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact with hands, eyes or mouth during specimen collection and testing.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
4. Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective

- decontamination. **NOTE:** Do not autoclave solutions that contain bleach.
- For additional information on biosafety, refer to “Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens.”¹¹ And “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.”¹³
 - Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.

Handling Precautions

- If Desiccant Packet is missing, DO NOT USE, discard test device, and a new test device should be used.
- Do not use any test device if the pouch has been perforated.
- Each test device is for single use only.
- Do not use the reagents beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
- Do not mix reagents from different lot numbers of Kits.
- Adequate lighting is required to read the Test Results.

STORAGE

The Chembio HIV 1/2 STAT-PAK[®] Assay should be stored in its unopened pouch at 8 to 30°C (46 to 86°F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch. Running Buffer should also be stored at 8 to 30°C (46 to 86°F) in its original vial.

SPECIMEN COLLECTION

Prior to specimen collection, provide test subjects with Subject Information Notice and pre-test counseling according to CDC Guidelines for Rapid HIV Testing.⁷

The Chembio HIV 1/2 STAT-PAK[®] Assay is performed on fingerstick whole blood, venous whole blood, serum or plasma specimens.

Fingerstick Whole Blood: Prepare to perform the fingerstick blood collection procedure. Clean the finger of the person being tested with an antiseptic wipe. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.

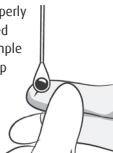
Using a sterile lancet, puncture the skin just off the center of the finger and wipe away the first drop with sterile gauze and avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.

Collect the sample from the second drop touching the disposable Sample Loop provided to the drop of blood until the Sample Loop is full. Test immediately, following Test Procedure Instructions.

Venous Whole Blood: Draw blood following laboratory procedures for obtaining venous blood. Collect sample in a tube containing citrate, heparin, or EDTA. Be sure the tube of blood is well mixed before sampling. Dip the Sample Loop into the blood and allow it to fill.

If tested the same day, venous whole blood may be kept at room temperature.

Properly
filled
Sample
Loop



Sampling from
a sample tube
containing
citrate, heparin
or EDTA



Venous whole blood may be stored for up to 3 days between 2 and 8°C (36 to 46°F) before testing.

DO NOT FREEZE WHOLE BLOOD! Allow refrigerated sample to reach room temperature and mix gently before testing.

Serum or Plasma: [NOTE: Serum and Plasma may only be tested in laboratories certified to run moderate complexity tests.] Draw blood following laboratory procedures for obtaining serum or plasma specimens. Collect specimen in a tube not containing any anticoagulant (serum), and in a tube containing citrate, heparin, or EDTA (plasma). Collect specimen in a clean container following standard laboratory procedures.

Serum and plasma specimens may be tested immediately after collection. If specimens are not tested immediately, refrigerate them at 2 to 8°C (36 to 46°F) following collection. These specimens should be tested within 3 days of collection. If specimens are not tested within 3 days of collection, serum or plasma specimens should be frozen at -20°C (-4°F) or colder.

Specimen Shipping

If specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents. Venous whole blood, serum and plasma specimens should be shipped refrigerated with cold packs or wet ice.

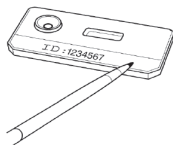
TEST PROCEDURE FOR CLIA WAIVED AND CLIA MODERATE SETTINGS

Kit Component Preparation

All components for the Chembio HIV 1/2 STAT-PAK® Assay test are ready to use as supplied. Follow directions as indicated. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F) prior to testing.

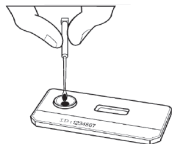
1. Remove the Chembio HIV 1/2 STAT-PAK® test device from its pouch and place it on a flat surface (It is not necessary to remove the desiccant from the pouch). Note: If Desiccant Packet is missing, DO NOT USE, discard test device and a new test device should be used
2. Label the test device with patient name or ID number. (See Figure 1)

Figure 1



3. Touch the 5µL sample loop provided to the specimen, allowing the opening of the loop to fill with the liquid.
4. Holding the sample loop vertically, touch it to the sample pad in the center of the SAMPLE (S) well of the device to dispense ~5µL of sample (serum, plasma or whole blood) onto the sample pad. (See Figure 2)

Figure 2



5. Invert the Running Buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (~ 105µL) of buffer slowly, dropwise, into the SAMPLE (S) well. (See Figure 3)

Figure 3



6. Read the Test Result between 15 and 20 minutes after the addition of the Running Buffer. Reactive Test Results (See Interpretation of Test Results section) may be observed and read earlier than 15 minutes. To verify a Nonreactive Test Result, wait the entire 15 minutes after starting the test. Do not read results after 20 minutes.

NOTE: Discard the used Sample Loop, Test Device and any other test materials into a biohazard waste container.

QUALITY CONTROL

Built-in Control Feature

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the CONTROL (C) area if the test has been performed correctly and the device is working properly (Please see section: Interpretation of Test Results).

External Quality Control

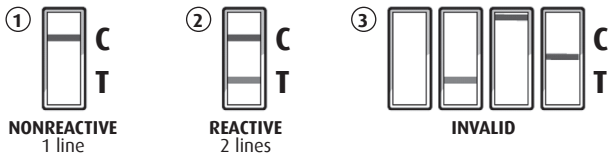
Good Laboratory Practices (GLP) necessitates testing external control material along with the test samples to ensure proper performance of the test Kit. Chembio HIV Reactive/Nonreactive Controls (Catalog # 60-9549-0) are available separately for use with the Chembio HIV 1/2 STAT-PAK® Assay. The HIV Controls are used to verify the operator's ability to properly perform the test and to interpret the results. Each Reactive Control will produce a REACTIVE Test Result and has been manufactured to produce a faint line in the TEST (T) area. The Nonreactive Control will produce a NONREACTIVE Test Result. Run the Controls as per the TEST PROCEDURE and follow the instructions as described in INTERPRETATION OF TEST RESULTS sections of this Product Insert. It is the responsibility of each facility using the Chembio HIV 1/2 STAT-PAK® assay to establish an adequate quality assurance program to ensure the performance of the device under specific locations and conditions of use.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing tests on patient specimens,
- When opening a new test Kit lot,
- Whenever a new shipment of test Kits is received,
- If the temperature of the test storage area falls outside of 8 to 30°C (46 to 86°F),
- If the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F),
- At periodic intervals as indicated by the user facility.

If the HIV Control reagents do not produce the expected results, contact Chembio Diagnostic Systems Customer Service at (631) 924-1135 or Toll Free at 1-800-327-3635.

INTERPRETATION OF TEST RESULTS FOR CLIA WAIVED AND CLIA MODERATE SETTINGS



NONREACTIVE (See Diagram 1):

One pink/purple line in the CONTROL (C) area, with no line in the TEST (T) area, indicates a NONREACTIVE Test Result. A NONREACTIVE Test Result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The Test Result is interpreted as NEGATIVE for HIV-1 and HIV-2 antibodies. However, this does not exclude possible infection with HIV. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.^{7, 14}

REACTIVE (See Diagram 2):

Two pink/purple lines, one in the TEST (T) area and one in the CONTROL (C) area, indicate a REACTIVE Test Result. The line in the TEST (T) area may look different from the line in the CONTROL (C) area. Intensities of the Test and Control Lines may vary. Test Result with visible lines in both TEST (T) and CONTROL (C) areas, regardless of intensity, is considered REACTIVE. A Reactive Test Result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The Test Result is interpreted as Preliminary POSITIVE for HIV-1 and/or HIV-2 antibodies. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.^{7, 14}

INVALID (See Diagram 3):

A pink/purple line should always appear in the CONTROL (C) area, whether or not a line appears in the TEST (T) area. If there is no distinct pink/purple line visible in the CONTROL (C) area, then the test is INVALID.

Any line that appears outside of the Control (C) Area of Test (T) Area is an INVALID test. An INVALID test cannot be interpreted. It is recommended that the INVALID test be repeated with a new device.

LIMITATIONS OF THE PROCEDURE

1. The Chembio HIV 1/2 STAT-PAK[®] test must be used in accordance with the instructions in this Product Insert to obtain accurate results.
2. The Chembio HIV 1/2 STAT-PAK[®] Assay must be used with capillary (fingerstick) or venous whole blood, serum or plasma only. Use of other types of specimens or testing of venipuncture whole blood specimens collected using a tube containing an anticoagulant other than citrate, heparin or EDTA may not yield accurate results. For serum samples, collect blood without anticoagulant.
3. Reading Nonreactive Test Results earlier than 15 minutes or any Test Results later than 20 minutes may yield erroneous results.
4. Do not open the sealed foil pouch until just prior to use.
5. Do not use Kit contents beyond labeled expiration date.
6. For the collection of the fingerstick whole blood specimen, ensure that finger is completely dry before performing fingerstick.
7. Read results in a well-lit area.

8. A Reactive Test Result using the Chembio HIV 1/2 STAT-PAK® test suggests the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The Chembio HIV 1/2 STAT-PAK® Assay is intended as an aid in the diagnosis of infection with HIV-1/2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.
9. For a Reactive Test Result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
10. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that 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.
11. A Nonreactive Test Result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
12. This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 13 years.

PERFORMANCE CHARACTERISTICS

The Chembio HIV 1/2 STAT-PAK® Assay was evaluated in prospective clinical studies at four geographically distinct sites. The specimens were tested from three groups of individuals: Known infected with HIV-1, at high risk for infection with HIV-1, and at low risk for infection with HIV-1. The Chembio HIV 1/2 STAT-PAK® Assay was tested in parallel on fingerstick whole blood, venous whole blood, serum and plasma specimen matrices. No discordant result was obtained from all specimen matrices. The serum/plasma specimens from study subjects were also tested using a licensed Enzyme Immunoassay (EIA). Specimens with discordant results were further tested using licensed Western Blot and/or FDA approved NAT assay.

SENSITIVITY

The sensitivity of the Chembio HIV 1/2 STAT-PAK® Assay to detect infection with HIV-1 was evaluated using 613 specimens from individuals known to be infected with HIV-1 and from 776 individuals at high risk for infection with HIV-1 (Table 1). 647 individuals were identified as positive for infection with HIV-1 using a licensed confirmatory Assay, and/or FDA approved NAT assay. Of these, 645 tested reactive on the Chembio HIV 1/2 STAT-PAK® Assay. The calculated sensitivity of Chembio HIV 1/2 STAT-PAK® assay in these studies was 99.7% ($645/647 = 99.7\%$ with 95% CI = 98.9% - 100%).

Table 1
Detection of antibody to HIV-1 in specimens from individuals known to be infected with HIV-1, and at high risk for infection with HIV-1

Study Population	Samples	HIV 1/2 STAT-PAK® Assay Reactive	Licensed EIA Repeatedly Reactive	Licensed WB Reactive	True Positive ¹
Known Positive	613	609	611	611	611
High-Risk	776	36	41	35 ²	36 ³
TOTAL	1389	645	652	646	647

1. Based on licensed WB and NAT assay results (when positive and EIA is repeatedly reactive).

2. Two specimens were indeterminate by Western Blot (one was initially reactive only on EIA and Nonreactive on HIV 1/2 STAT-PAK®, and one was repeatedly reactive on EIA and Nonreactive on HIV 1/2 STAT-PAK®).

3. One specimen was repeatedly reactive on EIA and Reactive on HIV 1/2 STAT-PAK®, indeterminate on WB, and positive on NAT.

The Sensitivity of the Chembio HIV 1/2 STAT-PAK® Assay to detect HIV-2 antibody was determined by testing 202 serum/plasma specimens that were positive for HIV-2 antibodies only. These specimens were obtained from repository sources. A total of 488 specimens from an area endemic for HIV-2 infection were also tested (Table 2). All specimens reactive with the Chembio HIV 1/2 STAT-PAK® in these studies were also reactive by a licensed anti-HIV-1/2 EIA. The sensitivity of HIV 1/2 STAT-PAK® for detection of antibodies to HIV-2 in these studies was calculated to be 100% (203/203 = 100% with 95% CI = 98.2% - 100%).

Table 2
Detection of antibody to HIV-2 in known HIV-2 reactive specimens and endemic samples

Study Population	Samples	HIV 1/2 STAT-PAK® Assay Reactive	True HIV-2 Positive Only ¹
Known HIV-2 Positive	202	202	202
Endemic Samples	488	27 ²	1
TOTAL	690	229	203

1. Confirmation based on results using a research use HIV-2 Western blot.

2. Of these 27 HIV-1 EIA and HIV-2 EIA reactive specimens; 23 were reactive on HIV-1 WB only, three were reactive on HIV-1 and HIV-2 WB, and one was indeterminate on HIV-1 WB and reactive on HIV-2 WB.

REACTIVITY WITH HIV-1 SPECIMENS FROM VARIOUS WORLD WIDE GEOGRAPHIC REGIONS

To assess sensitivity of the Chembio HIV 1/2 STAT-PAK® Assay for HIV-1 specimens from various worldwide geographic regions, 1,894 confirmed HIV antibody-positive specimens were obtained. Of the 1,859 specimens evaluated from Africa, Asia, Latin America, Europe, and Belgium, 1,854 were reactive using Chembio HIV 1/2 STAT-PAK® Assay. The remaining 35 confirmed positive specimens, from two worldwide panels were evaluated, consisting of naturally occurring plasma specimens from diverse geographical locations (Spain, Ghana, Cote d' Ivoire, Mozambique, Uganda, Zimbabwe, China, Thailand, India, USA and Argentina with HIV-1 genotypes: A, B, C, D, E, F, G, O, B/D and HIV-2). All 35 were reactive using Chembio HIV 1/2 STAT-PAK® Assay.

REACTIVITY WITH SEROCONVERSION PANELS

The Chembio HIV 1/2 STAT-PAK® Assay was tested against 15 different seroconversion panels. Each panel consisted of sequential collections from a single individual who seroconverted. Samples were confirmed using Western Blot (WB) and two licensed EIA tests. As shown in Table 3, the Chembio HIV 1/2 STAT-PAK® test performed similarly to currently licensed assays in detecting seroconversion.

Table 3
Comparison of the Chembio HIV 1/2 STAT-PAK® Assay to two licensed EIA assays and Western Blot in detecting seroconversion.
(Where NR = Nonreactive and RR = Repeatedly Reactive)

Panel	Relative Day of Bleed	Chembio HIV 1/2 STAT-PAK® Assay	EIA 1	EIA 2	WB
PRB-927 (AB)	0	NR	NR	NR	NR
	28	NR	RR	NR	NR
	33	NR	RR	NR	NR
	35	R	RR	NR	NR
	40	R	RR	RR	R
PRB-928 (AC)	0	NR	NR	NR	NR
	111	NR	RR	NR	NR
	120	R	RR	RR	R
	125	R	RR	RR	R
	130	R	RR	RR	R
PRB-930 (AE)	0	NR	NR	NR	NR
	3	NR	NR	NR	NR
	7	NR	RR	NR	NR
	10	NR	RR	RR	IND
PRB-931 (AF)	0	NR	NR	NR	NR
	2	NR	NR	NR	NR
	7	NR	NR	NR	NR
	9	NR	NR	NR	NR
	15	NR	NR	NR	NR
	28	R	RR	NR	NR
	33	R	RR	RR	IND
	35	R	RR	RR	R
42	R	RR	RR	R	
PRB-934 (AI)	0	NR	NR	NR	NR
	7	R	RR	NR	IND
	11	R	RR	RR	IND
PRB-938 (AM)	0	NR	NR	NR	NR
	3	NR	NR	NR	NR
	9	NR	RR	NR	IND

Panel	Relative Day of Bleed	Chembio HIV 1/2 STAT-PAK® Assay	EIA 1	EIA 2	WB
PRB-944 (AT)	0	NR	NR	NR	NR
	2	NR	NR	NR	NR
	7	NR	NR	NR	NR
	9	NR	NR	NR	NR
	14	R	RR	NR	IND
	16	R	RR	NR	IND
PRB-959 (BI)	0	NR	NR	NR	NR
	7	NR	NR	NR	NR
	9	NR	RR	NR	NR
	14	R	RR	RR	R
	19	R	RR	RR	R
	21	R	RR	RR	R
	26	R	RR	RR	R
PRB-904 (D)	0	NR	NR	NR	NR
	21	NR	NR	NR	NR
	49	NR	NR	NR	NR
	92	R	RR	RR	R
	99	R	RR	RR	R
PRB-910 (J)	0	NR	NR	NR	NR
	14	NR	NR	NR	NR
	26	R	RR	RR	R
	28	R	RR	RR	R
	32	R	RR	RR	R
	35	R	RR	RR	R
	40	R	RR	RR	R
PRB-914 (N)	0	R	RR	NR	IND
	4	R	RR	RR	IND
	7	R	RR	RR	IND
	25	R	RR	RR	R
	31	R	RR	RR	R
PRB-916 (P)	0	NR	NR	NR	NR
	4	NR	NR	NR	NR
	9	NR	NR	NR	NR
	15	NR	NR	NR	NR
	30	R	RR	RR	R
	35	R	RR	RR	R

Panel	Relative Day of Bleed	Chembio HIV 1/2 STAT-PAK® Assay	EIA 1	EIA 2	WB
PRB-917 (Q)	0	NR	NR	NR	NR
	53	NR	NR	NR	NR
	57	NR	NR	NR	NR
	60	N/A*	RR	NR	NR
	65	R	RR	NR	IND
	67	R	RR	NR	IND
PRB-919 (S)	72	N/A*	RR	RR	R
	0	NR	NR	NR	NR
	9	R	RR	NR	R
PRB-922 (V)	11	R	RR	RR	R
	0	NR	RR	NR	NR
	4	NR	RR	NR	NR
	7	R	RR	NR	NR
	11	R	RR	NR	R

*N/A - NOT AVAILABLE

REACTIVITY WITH HIV-1 LOW TITER PANELS

A total of 30 specimens from two characterized Low Titer panels were used to evaluate the ability of the Chembio HIV 1/2 STAT-PAK® Assay to detect antibodies to HIV-1. The results of testing are presented in Table 4 and demonstrate that the Chembio HIV 1/2 STATPAK® Assay detected the presence of antibody in a manner similarly to one or both of the licensed EIAs.

Table 4
Comparison of the Chembio HIV 1/2 STAT-PAK® Assay to two licensed EIA assays and Western Blot using Low Titer panels
(Where NR = Nonreactive and RR = Repeatedly Reactive)

Panel	Chembio HIV 1/2 STAT-PAK® Assay	EIA 1	EIA 2	WB
PRB107-1	NR	RR	NR	NR
PRB107-2	NR	RR	RR	IND
PRB107-3	NR	RR	NR	NR
PRB107-4	NR	RR	RR	NR
PRB107-5	NR	NR	NR	NR
PRB107-6	R	RR	RR	NR
PRB107-7	NR	RR	NR	NR
PRB107-8	NR	RR	RR	NR
PRB107-9	NR	RR	NR	NR
PRB107-10	R	RR	RR	NR
PRB107-11	R	RR	RR	R

Panel	Chembio HIV 1/2 STAT-PAK® Assay	EIA 1	EIA 2	WB
PRB107-12	NR	RR	NR	NR
PRB107-13	NR	RR	NR	IND
PRB107-14	R	RR	RR	R
PRB107-15	R	RR	RR	IND
PRB108-1	R	RR	RR	R
PRB108-2	NR	NR	NR	NR
PRB108-3	NR	RR	RR	IND
PRB108-4	R	RR	RR	R
PRB108-5	R	RR	RR	R
PRB108-6	R	RR	RR	IND
PRB108-7	R	RR	RR	R
PRB108-8	R	RR	RR	R
PRB108-9	R	RR	RR	R
PRB108-10	NR	RR	NR	IND
PRB108-11	R	RR	RR	R
PRB108-12	NR	RR	NR	NR
PRB108-13	NR	RR	NR	IND
PRB108-14	NR	RR	NR	NR
PRB108-15	R	RR	RR	IND

REACTIVITY WITH HIV-1 MIXED TITER PANELS

The sensitivity of Chembio HIV 1/2 STAT-PAK® Assay was evaluated by testing three well characterized panels composed of specimens ranging from nonreactive to strong reactive for anti-HIV-1 antibody. The results are presented in Table 5 and indicate that the Chembio HIV 1/2 STAT-PAK® Assay was able to detect antibodies to HIV-1 similarly to the licensed EIA and WB.

Table 5

Comparison of the Chembio HIV 1/2 STAT-PAK® Assay to two licensed EIA assays and Western Blot using Mixed Titer Panels (Where NR = Nonreactive and RR = Repeatedly Reactive)

Panel	Chembio HIV 1/2 STAT-PAK® Assay	EIA 1	EIA 2	WB
PRB202-1	NR	RR	RR	IND
PRB202-2	R	RR	RR	R
PRB202-3	R	RR	RR	R
PRB202-4	R	RR	RR	R
PRB202-5	R	RR	RR	R
PRB202-6	R	RR	RR	R
PRB202-7	R	NR	RR	R

Panel	Chembio HIV 1/2 STAT-PAK® Assay	EIA 1	EIA 2	WB
PRB202-8	R	RR	RR	R
PRB202-9	NR	NR	NR	NR
PRB202-10	R	RR	RR	R
PRB202-11	R	RR	RR	R
PRB202-12	R	RR	RR	R
PRB202-13	NR	RR	RR	R
PRB202-14	R	RR	RR	R
PRB202-15	R	RR	RR	R
PRB202-16	R	RR	RR	R
PRB202-17	R	RR	RR	R
PRB202-18	R	RR	RR	R
PRB202-19	R	RR	RR	R
PRB202-20	R	RR	RR	R
PRB202-21	NR	NR	NR	NR
PRB202-22	R	RR	RR	R
PRB202-23	NR	RR	NR	IND
PRB202-24	R	RR	RR	R
PRB202-25	R	RR	RR	R
PRB203-1	R	RR	RR	R
PRB203-2	R	RR	RR	R
PRB203-3	NR	NR	NR	NR
PRB203-4	NR	RR	NR	IND
PRB203-5	R	RR	RR	R
PRB203-6	R	RR	RR	R
PRB203-7	R	RR	RR	R
PRB203-8	R	RR	RR	R
PRB203-9	R	RR	RR	R
PRB203-10	R	RR	RR	R
PRB203-11	R	RR	RR	R
PRB203-12	R	RR	RR	R
PRB203-13	R	RR	RR	R
PRB203-14	NR	RR	NR	NR
PRB203-15	R	RR	RR	R
PRB203-16	R	RR	RR	R
PRB203-17	R	RR	RR	R
PRB203-18	R	RR	RR	R

Panel	Chembio HIV 1/2 STAT-PAK® Assay	EIA 1	EIA 2	WB
PRB203-19	R	RR	RR	R
PRB203-20	NR	NR	NR	NR
PRB203-21	R	RR	RR	R
PRB203-22	R	RR	RR	R
PRB203-23	R	RR	RR	R
PRB203-24	R	RR	RR	R
PRB203-25	R	RR	RR	R
PRB204-1	NR	RR	NR	NR
PRB204-2	R	RR	RR	R
PRB204-3	NR	NR	NR	NR
PRB204-4	R	RR	RR	R
PRB204-5	R	RR	RR	R
PRB204-6	R	RR	RR	R
PRB204-7	R	RR	RR	R
PRB204-8	R	RR	RR	R
PRB204-9	NR	RR	NR	NR
PRB204-10	R	RR	RR	IND
PRB204-11	R	RR	RR	R
PRB204-12	R	RR	RR	R
PRB204-13	NR	RR	RR	IND
PRB204-14	R	RR	RR	R
PRB204-15	R	RR	RR	R
PRB204-16	R	RR	RR	R
PRB204-17	R	RR	RR	R
PRB204-18	R	RR	RR	IND
PRB204-19	R	RR	RR	R
PRB204-20	R	RR	RR	R
PRB204-21	R	RR	RR	R
PRB204-22	R	RR	RR	R
PRB204-23	NR	NR	NR	NR
PRB204-24	NR	RR	NR	IND
PRB204-25	NR	RR	NR	IND

SPECIFICITY

The specificity of Chembio HIV 1/2 STAT-PAK® Assay was evaluated by testing specimens from low risk and high risk populations for infection with HIV-1 from three clinical study sites. The results are summarized in Table 6.

Table 6
Performance of the Chembio HIV 1/2 STAT-PAK® Assay on specimens from individuals presumed to be negative for HIV-1 infection

Study Population	Samples	HIV 1/2 STAT-PAK® Assay Nonreactive	Licensed EIA Nonreactive	True Negative ¹
Low-Risk	691	690	687 ²	691
High-Risk	776	740	735 ³	740
TOTAL	1467	1430	1422	1431

1. Confirmation performed by licensed HIV-1 Western Blot, IFA or NAT. One specimen was EIA repeatedly reactive, WB indeterminate, and NAT positive. One specimen was EIA repeatedly reactive and WB indeterminate. These two specimens were not included in the specificity calculations.
2. Four specimens were repeatedly reactive on EIA and nonreactive on Chembio HIV 1/2 STAT-PAK® Assay and Western Blot.
3. Five specimens were repeatedly reactive on EIA and nonreactive on Chembio HIV 1/2 STAT-PAK® Assay and Western Blot.

Based on these studies, the specificity of Chembio HIV 1/2 STAT-PAK® Assay in these studies was calculated to be 99.9% ($1430/1431 = 99.9\%$ with 95% CI = 99.6% - 100%).

EFFECT OF POTENTIALLY INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

To evaluate the influence of unrelated medical conditions or interfering substances on the specificity and sensitivity of the Chembio HIV 1/2 STAT-PAK® Assay, 208 specimens representing unrelated medical conditions, and 110 specimens representing potential interfering substances were tested (Table 7). The specimens were spiked with either saline (Nonreactive) or an HIV-1 reactive serum specimen to a low level of reactivity. All HIV-1 spiked specimens gave reactive results while all unspiked samples, with the exception of one elevated albumin specimen and 14 syphilis specimens, gave nonreactive results. The one elevated albumin specimen and all of the 14 unspiked syphilis specimens with reactive results were subsequently confirmed as infected with HIV-1 using a licensed Western Blot assay. An additional ten known HIV-1 nonreactive, syphilis reactive specimens were tested and yielded expected results.

Table 7
Chembio HIV 1/2 STAT-PAK® Assay reactivity against specimens
from unrelated medical conditions or containing potential interfering substances.

Chembio HIV 1/2 STAT-PAK® Assay		
Description	Saline (Nonreactive)	HIV-1/2 (Weak Reactive)
Cirrhosis	20/20	20/20
CMV IgM	20/20	20/20
Recent flu vaccination ¹	11/11	11/11
HBV	21/21	21/21
HCV	19/19	19/19
HTLV-I	11/11	11/11
HTLV-II	10/10	10/10
Multiparous	9/9	9/9
Myeloma	10/10	10/10
Rheumatoid Factor	10/10	10/10
Syphilis ²	15/29	29/29
Tuberculosis	38/38	38/38
Elevated Albumin ³	9/10	10/10
Elevated Bilirubin	10/10	10/10
Citrate	10/10	10/10
DNA	10/10	10/10
EDTA	10/10	10/10
Hemolyzed	10/10	10/10
Heparin	10/10	10/10
Icteric	10/10	10/10
Lipemic	10/10	10/10
Elevated Protein	10/10	10/10
Elevated Triglycerides	10/10	10/10

1. Collected within 6 months of vaccination

2. Fourteen samples were confirmed reactive, using a licensed WB assay

3. One sample was confirmed as containing HIV antibodies by using a licensed WB assay

REPRODUCIBILITY STUDIES

Reproducibility was tested at three independent sites using three lots of Chembio HIV 1/2 STAT-PAK® Assay. A panel of five blinded samples representing nonreactive, low reactive HIV-1, low reactive HIV-2, high reactive HIV-1 and high reactive HIV-2 were run on three separate days by three separate technicians at each site. Testing was performed according to the Product Insert of the Chembio HIV 1/2 STAT-PAK® test. Results were read at 15 minutes. Results were read semi-quantitatively using a common strip evaluation scale. A total of 405 data points was taken. There was 100% reproducibility (405/405) across all parameters.

RESULTS FROM UNTRAINED USER STUDY

An 'untrained user' study was conducted in which participants were given only the written test instructions and asked to perform testing on a masked panel of six whole blood specimens prepared at three different levels (negative, low positive and strong positive Chembio HIV 1/2 STAT-PAK® Assay reactivity). Study participants received no verbal or other instructions or training. The study protocol stipulated that professionally trained medical laboratory personnel or persons with prior experience using the Chembio HIV 1/2 STAT-PAK® Assay were excluded from participation. A total of 112 participants were enrolled from a total of four sites, representing a diverse demographic (educational, age, gender, ethnic, etc.). In order to help evaluate ease of use and clarity of the test instructions and interpretation of results, each participant was asked to complete a questionnaire and offer comments about their experience with the test.

The overall rate of correct results was 99.5% (646/649). The results of the study by specimen type are summarized below in Table 8. The overall rate of invalid results for all four sites was 3.9%.

Table 8
Untrained Users Rate of Correct Test Results

Negative	Low Positive	High Positive	Total
100% (216 / 216)	99.5% (214 / 215)	99.1% (216 / 218)	99.5% (646 / 649)
95% CI = 98.3% - 100%	95% CI = 97.4% - 100%	95% CI = 96.7% - 99.9%	95% CI = 98.7% - 99.9%

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REF 60-9505-1 Chembio HIV 1/2 STAT-PAK® Assay

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