WHO Prequalification of Diagnostics Programme
PUBLIC REPORT

Product: HIV 1/2 STAT-PAK®
Number: PQDx 0007-006-00

Abstract

The HIV 1/2 STAT-PAK® with product code HIV101, manufactured by Chembio Diagnostic Systems, Inc., 3661 Horseblock Road, Medford, NY 11763, United States of America, regulatory version “solely for export outside of the United States of America, except Nigeria”, was accepted for the WHO list of prequalified diagnostics and was listed on 16 January 2012.

The manufacturer also holds an FDA approved regulatory version of the HIV 1/2 STAT-PAK® (marketed as Clearview) with product code HIV102.

The HIV 1/2 STAT-PAK® is a single-use immunochromatographic rapid screening test for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The HIV 1/2 STAT-PAK® is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV 1 and HIV 2. The HIV 1/2 STAT-PAK® is not approved for use to screen blood, plasma, cell or tissue donors.

The HIV 1/2 STAT-PAK® 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 membrane solid phase. The sample is applied to the sample (S) well followed by the addition of running buffer. The buffer facilitates the lateral flow of the released products and promotes the binding of antibodies to the antigens. If present, the antibodies bind to the 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 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 the specimen and reagents have been properly applied and have migrated through the device.

A reactive result using the HIV 1/2 STAT-PAK® suggests the presence of antibodies to HIV 1 or HIV 2 in the specimen. The HIV 1/2 STAT-PAK® is intended as an aid in the diagnosis of
infection with HIV-1/2. HIV and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.

A nonreactive result at any time 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.

The test kit contains:
- 20 individually pouches test devices
- 1 HIV running buffer (3.5 ml)
- 20 disposable 5µl sample loops
- 1 instructions for use.

Storage:
The test kit should be stored at 8 - 30 °C.

Shelf-life upon manufacture:
24 months.

### Summary of prequalification status for the HIV 1/2 STAT-PAK®

<table>
<thead>
<tr>
<th></th>
<th>Initial acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date</strong></td>
<td><strong>Outcome</strong></td>
</tr>
<tr>
<td><strong>Status on PQ list</strong></td>
<td>16 January 2012</td>
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<tr>
<td><strong>Dossier assessment</strong></td>
<td>09 January 2012</td>
</tr>
<tr>
<td><strong>Inspection status</strong></td>
<td>21 November 2011</td>
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<tr>
<td><strong>Laboratory evaluation</strong></td>
<td>05 January 2012</td>
</tr>
</tbody>
</table>

MR: Meets Requirements
NA: Not Applicable

The HIV 1/2 STAT-PAK® was accepted for the WHO list of prequalified diagnostics on the basis of data submitted and publicly available information.
Background information

Chembio Diagnostic Systems, Inc. submitted an application for prequalification of the HIV 1/2 STAT-PAK®. Based on the established prioritization criteria, the HIV 1/2 STAT-PAK® was given priority for prequalification.

Product dossier assessment

Chembio Diagnostic Systems, Inc. submitted a product dossier for the HIV 1/2 STAT-PAK® as per the Instructions for compilation of a product dossier (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO in accordance with the internal report on the screening and assessment of a product dossier (PQDx_009 v2). Based on the product dossier screening and assessment findings, a recommendation was made to accept the product dossier for the HIV 1/2 STAT-PAK® for prequalification.

Commitments for prequalification:

The manufacturer committed to amend and submit additional documentation on the following issues:

1. Analytical performance studies
2. Clinical performance studies
3. A new version of labels and instructions for use.

Manufacturing site inspection

An abbreviated inspection was performed at the site of manufacture Chembio Diagnostic Systems, Inc. (3661 Horseblock Road, Medford, Long Island, 11763, NY, USA) of the HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick on 11-12 November 2010 as described in ‘Information for manufacturers on WHO prequalification inspection procedures for the sites of manufacture of diagnostics (PQDx_014 v1)’.

The inspection found that the manufacturer had a well-established quality management system and manufacturing practices in place that would ensure the manufacture of a product of consistent quality. The manufacturer's responses to the minor nonconformities and observations noted at the time of the inspection were accepted on 21 November 2011.

Commitments for prequalification:

1. Risk analysis criteria will be re-assessed at Chembio Diagnostic Systems, Inc. to consider specifications and formulations of products for use in resource limited and environmentally challenging regions to which the products are distributed. Further stability studies with high temperature, high humidity conditions will be undertaken.
2. Chembio Diagnostic Systems, Inc. has committed to implementing a revised customer feedback procedure, to seek information on product performance and
customer service from users in resource limited regions where communication may be problematic.

**Laboratory evaluation**

HIV 1/2 STAT-PAK® was evaluated by WHO in the fourth quarter of 2011 at the Institute of Tropical Medicine, Antwerp, Belgium – a WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support. The laboratory evaluation was conducted according to the “WHO Protocol for the laboratory evaluation of HIV serology assays” (PQDx_030 V1.0), and drew the following conclusions:

HIV 1/2 STAT-PAK® is an immunochromatographic rapid diagnostic test for the detection of antibodies to HIV-1/2 in human serum, plasma, and whole blood. A volume of 5µl of serum, plasma or venous/capillary whole blood is required to perform the test procedure. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities. Reading of the results are performed visually i.e. subjective reading.

In this limited performance evaluation using a panel of 1079 biological specimens, we observed an initial (sensitivity (95% CI) of 99.29% (97.9% - 100%) and an initial specificity (95% CI) of 100% (99.4% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 99.52% (98.3% - 100%) and the final specificity (95% CI) was 100% (99.4% - 100%) compared to the reference assays. In this study, 0% of the overall results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0.18%. The invalid rate was 0%. 
Labelling

1. Labels
2. Instructions for use
1. Labels
2. Instructions for use

HIV 1/2 STAT-PAK®
FOR IN VITRO DIAGNOSTIC USE
FOR PROFESSIONAL USE ONLY
A Qualitative Screening Test Kit for the Detection of Antibodies to HIV-1/2 in Human Fingerstick and Venous Whole Blood, Serum and Plasma
STORAGE: Store at 8 to 30°C (46 to 86°F)

INTENDED USE
The Chembio HIV 1/2 STAT-PAK is a single-use immunochromatographic, rapid screening test for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Chembio HIV 1/2 STAT-PAK 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 — The HIV 1/2 STAT-PAK is not approved for use to screen blood, plasma, cell or tissue donors.

SUMMARY AND EXPLANATION
Discovered in 1983, the Human Immunodeficiency Virus (HIV) is a retrovirus identified as the etiologic agent for Acquired Immunodeficiency Syndrome (AIDS) and AIDS related complex [1]. 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, contamination by blood or blood products and mother-to-newborn transmission [2-4].

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/AIDS in 2005. In the same year more than 3 million died of AIDS-related illness; more than 500,000 of these were children [5].

HIV infection, AIDS and AIDS related complex have become a leading cause of illness and death, globally, for the past two decades. As of 2009, a total of 1.8 million persons had died of AIDS or AIDS related complex. Approximately 33.3 million persons across the world are infected with HIV and approximately 20% of these persons may not be aware of their infected status. [6]
The HIV virus consists of a genomic RNA molecule protected by a capsid and an envelope. The HIV envelope is the major target for humoral antibody response. The presence of the virus in patients causes the immune system to elicit the production of antibodies to HIV. The detection of these antibodies can be used as a diagnostic tool.

ELISAs, Western Blots, PCR-based and various other test systems are currently available for HIV 1/2 detection [7-11]. The Chembio HIV 1/2 STAT-PAK is a rapid immunochromatographic test, which is simple and easy to use. The Chembio HIV 1/2 STAT-PAK utilizes immobilized antigens for the detection of antibodies to HIV 1/2 in serum, plasma or whole blood.

**PRINCIPLE OF THE TEST**
The Chembio HIV 1/2 STAT-PAK 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 membrane solid phase. The sample is applied to the sample (S) well followed by the addition of running buffer. The buffer facilitates the lateral flow of the released products and promotes the binding of antibodies to the antigens. If present, the antibodies bind to the 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 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 items to perform 20 tests:
- 20 STAT-PAK Individually Pouched Test Devices
- 1 HIV Running Buffer (3.5mL)
- 20 Disposable 5mL Sample Loops
- 1 Product Insert

**MATERIALS AVAILABLE AS AN ACCESSORY TO THE KIT**
Chembio Rapid HIV 1/2 Antibody Test Kit Controls (Catalogue # HIV104)
Each package contains:
- HIV 1 Reactive Control
- HIV 2 Reactive Control
- Nonreactive Control
- Product Insert for the HIV104

**MATERIALS REQUIRED BUT NOT PROVIDED**
- Clock, watch or other timing device
- Automatic pipettor capable of delivering 5 μL of sample may be used in lieu of the disposable 5 μL sample loop supplied with the kit, for other than fingerstick specimens
- Disposable gloves
- Sterile gauze (for fingerstick whole blood specimens)
- Sterile alcohol swab (for fingerstick samples only)
- Biohazard disposal container
- Sterile lancet (for fingerstick samples only)
- Collection devices for samples other than fingerstick
WARNINGS
For in-vitro diagnostic use

1. Read the Product Insert completely before using this assay. Following the instructions carefully as not doing so may result in inaccurate test results.
2. Use of this test kit with specimen types other than those specifically approved for use with this device may result in inaccurate test results.
3. This test should be performed at 18-30°C (64 to 86°F). If stored refrigerated, ensure that the pouch is brought to operating temperature before performing testing.
4. If the test kit is stored at temperatures outside the storage temperature 8-30°C (46 to 86°F), or used outside the operating temperature 18-30°C (64 to 86°F), use the Kit Controls (Catalogue HIV104) to ensure proper performance of the test.
5. Individual(s) infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce negative results.

PRECAUTIONS
Safety Precautions

1. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact between hands, eyes or mouth during specimen collection and testing.
2. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient specimens.
3. 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.

4. For additional information refer to: Centers for Disease Control (CDC): Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis [12].

Handling Precautions

1. Do not use any device if the pouch has been perforated.
2. If desiccant packet is missing, DO NOT USE, discard test device, and a new test device should be used.
3. Each device is for single use only.
4. Always check expiration date prior to testing. Do not use the test beyond the expiration date printed on the pouch.
5. Do not mix reagents from different lot numbers of kits.
6. Adequate lighting is required to read the test results.

STORAGE AND STABILITY
The HIV 1/2 STAT-PAK test devices should be stored in unopened pouches at 8 to 30°C (46 to 86°F). Do not freeze. Do not use beyond the indicated expiration date. Test devices are vacuum packed and the expiration date is marked on the pouch, when stored as indicated. Running Buffer should be stored at 8 to 30°C (46 to 86°F) in the original vial.
SPECIMEN COLLECTION
The Chembio HIV 1/2 STAT-PAK test can be performed on fingerstick whole blood, venous whole blood, serum or plasma specimens. All specimens should be collected following local clinical or laboratory procedures.

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 sterile lancet, following laboratory procedure; prick the finger just off the center of the finger and wipe away the first drop with sterile gauze. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.

Collect the sample from the second drop by 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 procedure for obtaining venous blood. Depending on use, 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. Follow test procedure instructions.

If tested the same day, venous whole blood may be kept at room temperature. 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 for refrigerated sample to reach room temperature and mix gently before testing.

Serum or Plasma
Draw blood following laboratory procedures for obtaining serum or plasma specimens. Collect specimen in a clean tube not containing any anticoagulant (serum) or in a tube containing citrate, heparin or EDTA (plasma), following standard laboratory procedures. All specimens should be centrifuged following local clinical or laboratory procedures.

Patient samples perform best when tested immediately after collection. If not tested immediately, specimens should be refrigerated at 2 to 8°C (36 to 46°F) and can be used up to 3 days after collection. If testing within 3 days is not possible, serum or plasma specimens should be frozen at -20°C (-4°F) or colder.

NOTE: 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
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 the test device and a new
test device should be used.

2. Label the test device with patient name or identification number. (See Figure 1 below)

   Figure 1

3. Touch the 5 µL 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 ~5 µL of sample (serum, plasma or whole
   blood) onto the sample pad. (See Figure 2 below)

   Figure 2

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

   Figure 3

6. Read the test result 15 minutes after the addition of the Running Buffer. In some cases
   a test line may appear in less than 15 minutes however, 15 minutes are needed to
report a nonreactive result. Read results in a well-lit area. 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. Do not re-use loops.

QUALITY CONTROL
Built-in Control Feature
When the test is complete, you will see a pink/purple line in the CONTROL (C) area of the test device on nonreactive as well as reactive samples. This control line serves as an 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 RESULTS).

External Quality Control
Good Laboratory Practices necessitates testing external control material along with the test samples to ensure proper performance of the test kit. Chembio HIV Reactive and Nonreactive Controls (Catalogue # HIV104) are available separately for use with the Chembio HIV 1/2 STAT-PAK test. The HIV Controls are used to verify the operator’s ability to properly perform the test and to interpret the results. The 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 INTERPRETATION OF RESULTS sections of this insert. It is the responsibility of each facility using the HIV 1/2 STAT-PAK to establish an adequate quality assurance program to ensure the performance of the device under specific locations and conditions.

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 (+1-631-924-1135).
**INTERPRETATION OF RESULTS**

**Nonreactive Results**

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 at 15 minutes indicates that HIV-1 and HIV-2 antibodies were not detected in the specimen. Test result is interpreted as NEGATIVE for HIV-1 and HIV-2 antibodies. However, this result does not exclude the possibility of HIV infection.

**Reactive Results**

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 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 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.

**NOTE:** Intensities of the TEST (T) and CONTROL (C) lines may vary. If any visible line appears in the TEST (T) area and in the CONTROL (C) area, the result is reactive.

Chembio HIV 1/2 STAT-PAK®
Invalid Results:

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 or TEST (T) area is an INVALID test. An INVALID test indicates a problem with running the test, either related to the specimen or to the device and cannot be interpreted. It is recommended that the INVALID test be repeated with a new device. Contact Chembio Diagnostic Systems at +1-631-924-1135 ext 114 or info@chembio.com if you are unable to obtain a valid result upon repeat testing.

LIMITATIONS OF THE PROCEDURE

1. The Chembio HIV 1/2 STAT-PAK must be used with capillary (fingerstick) or venous whole blood, serum or plasma only. Using 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.

2. The Chembio HIV 1/2 STAT-PAK must be used in accordance with the instructions in this product insert to obtain accurate results.

3. Be careful not to add more than 3 drops of Running Buffer with blood sample as it may lead to the appearance of a red line at the base of the window.

4. Reading test results earlier than 15 minutes or later than 20 minutes may yield erroneous results.

5. Test devices should be used immediately upon opening the sealed foil pouch.

6. Do not use kit contents beyond labeled expiration date.

7. Ensure finger is completely dry before performing fingerstick.

8. Read results in a well-lit area.

9. A reactive result using the Chembio HIV 1/2 STAT-PAK suggests the presence of antibodies to HIV-1 or HIV-2 in the specimen. The Chembio HIV 1/2 STAT-PAK is intended as an aid in the diagnosis of infection with HIV-1/2. HIV and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.

10. For a reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.

11. A nonreactive 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. An individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce false negative results.

13. This assay has not been evaluated for newborn screening, cord blood specimens, or for individuals less than 13 years of age or older than 64 years of age.
EXPECTED RESULTS
This is a qualitative test for the detection of antibodies to HIV 1/2 in whole blood, serum or plasma. As described in the PERFORMANCE CHARACTERISTICS section below, the sensitivity of the Chembio HIV 1/2 STAT-PAK was found to be substantially equivalent to EIA and Western Blot tests when tested on selected performance panels.

PERFORMANCE CHARACTERISTICS
In-house studies demonstrate that the sensitivity of the Chembio HIV 1/2 STAT-PAK is substantially equivalent to the EIA and Western Blot test when tested on BBI performance panels PRZ204 Anti-HIV 1 / 2 Combo Performance Panel, PRF202 Anti-HIV 2 Performance Panel and PRB203 Anti-HIV 1 Mixed Titer Performance Panel as well as BBI Seroconversion panels PRB904 and PRB909.

In an external evaluation of the performance of the HIV 1/2 STAT-PAK using 336 confirmed nonreactive and reactive sera, plasma and whole blood samples, sensitivity was 100% (129/129) and specificity, 100% (207/207). This study also included 34 fingerstick blood samples; 29 reactive and 5 nonreactive. In this same study, excellent analytical sensitivity relative to EIA was demonstrated using BBI seroconversion panels, PRB940 and PRB931.

EFFECT OF POTENTIALLY INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS
To evaluate the influence of unrelated medical conditions or interfering substance on the specificity and sensitivity of the Chembio HIV 1/2 STAT-PAK, 208 specimens representing unrelated medical conditions and 110 specimens representing potential interfering substances were tested (Table 1). 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 unspike 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>
<thead>
<tr>
<th>Description</th>
<th>Saline (Nonreactive)</th>
<th>HIV-1/2 (Weak Reactive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cirrhosis</td>
<td>20/20</td>
<td>20/20</td>
</tr>
<tr>
<td>CMV IgM</td>
<td>20/20</td>
<td>20/20</td>
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<tr>
<td>Recent flu vaccination&lt;sup&gt;1&lt;/sup&gt;</td>
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<tr>
<td>HBV</td>
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<tr>
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<tr>
<td>Tuberculosis</td>
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<tr>
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</tr>
<tr>
<td>Elevated Triglycerides</td>
<td>10/10</td>
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</table>

<sup>1</sup> Collected within 6 months of vaccination
<sup>2</sup> Fourteen samples were confirmed reactive, using a licensed WB assay
<sup>3</sup> One sample was confirmed as containing HIV antibodies by using a licensed WB assay

**PRECISION**

**Intraassay**

Within run precision was determined by using 10 replicates of two specimens containing different levels of HIV 1/2 antibodies. The nonreactive and reactive results were correctly identified 100% of the time.

**Interassay**

Between run precision was determined by using the same two specimens in 10 different replicates from three different lots of test devices. Again nonreactive and reactive results were observed 100% of the time.