One Step HIV 1/2 Test Disk
for Plasma or Serum
(Revised November, 2006)

EXPLANATION OF THE TEST
HIV-1 has been isolated from patients with AIDS and AIDS related complex, and from healthy persons with high potential risk of developing AIDS. Patients with HIV-2 are found primarily in parts of West Africa. HIV-1 and HIV-2 are similar in their morphology, cell tropism, host interaction and generic structure. Serological studies have determined that HIV-1 and HIV-2 have multiple common epitopes in core antigens but much less so in the envelope antigens.

The One Step HIV-1/HIV-2 test is a solid phase immunochromatographic assay for the qualitative detection of antibodies against HIV-1 and HIV-2. This test is intended for professional use as an aid on the diagnosis of HIV-1/HIV-2.

MATERIALS PROVIDED
1. HIV ½ test device.
2. Instructions.
3. Disposable sample dropper.
4. Dilution Buffer.

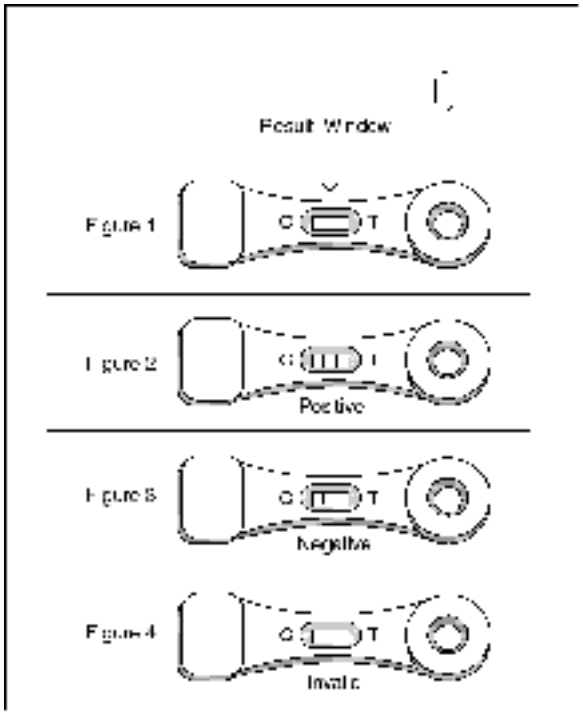
PRECAUTIONS
The One Step HIV-1/HIV-2 Test devices should be stored at 4 to 30ºC (40-86ºF). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

SPECIMEN COLLECTION AND STORAGE
1. The test must be performed using human serum or plasma.
2. If specimens are not immediately tested they should be refrigerated at 2-8 ºC. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS
1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE
1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk slowly add 1 drop of sample into the sample well (Figure 1), Then add 2 drops of dilution buffer.
3. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Disk.
4. Interpret test results at 15 to 20 minutes. Do not interpret test result after 20 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 ºC. If your room temperature is significantly lower than 15 ºC, then the interpretation time should be properly increased.



Interpretation of the Test
1. A color band will appear at the left section of the Result Window to show that the test is working properly. This band is the Control Band.
2. The right section of the Result Window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Band.

Positive Result
The presence of two color bands ("T" band and "C" band) within the result window no matter which band appears first indicates that antibodies against HIV-1/HIV-2 are detected (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.

Negative Result
The presence of only one purple color band within the result window indicates that antibodies against HIV-1/HIV-2 are not detected (Figure 3).

Invalid Result
If after performing the test no band is visible within the Result Window, the result is considered invalid (Figure 4). Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

Limitations of the Test
Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers for Disease Control. For samples repeatedly testing positive, more specific supplemental tests must be performed. Immuno-chromatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1/HIV-2 are present in a patient specimen. A negative result at any time does not preclude the possibility of HIV-1/HIV-2 infection.

Performance Characteristics
No standards for performance have yet been established for HIV rapid assays. The One Step HIV-1/HIV-2 test has been tested against a commercially available HIV panel with a commercially available ELISA HIV assay. All samples in the HIV panel detected as positive by the ELISA assay were also detected by One Step HIV-1/HIV-2 as positive. No cross reactivity or interference was detected from other antigens, lipemic, or icteric samples.

Specificity and Interference Studies
An in-house study was conducted with 3 separate lots of the HIV-1/HIV-2 test. Specimens tested include Serum with triglyceride concentrations up to 500 mg/ml, Serum with Bilirubin concentrations up to 10 mg/100ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml. All of the above were analyzed and did not show interference or cross reactivity with the test.

References

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4. Cumming PD, Wallace EL, Schorr JB, et al, "Exposure of Patients to Human Immunodeficiency Virus Through the Transfusion of Blood Components That Test Antibody-Negative," *N Engl J Med*, 1989, 321(14):941-6.
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