Anti-HIV Triline Cassette
Serum/Whole Blood Test

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 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 intend for professional use as an aid on the diagnostis of HIV-1/HIV2.

MATERIALS PROVIDED

1. HIV ½ test device.
2. Instructions.
3. Disposable sample droppers.
4. Dilution Buffer.

PRECAUTIONS

The 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. Perf orm 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/plasma or whole blood.
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. Whole blood cannot be stored in freezer.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

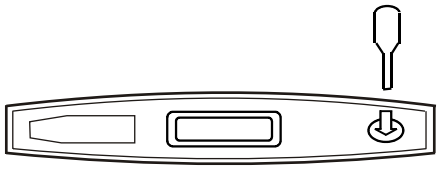
WARNINGS

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.

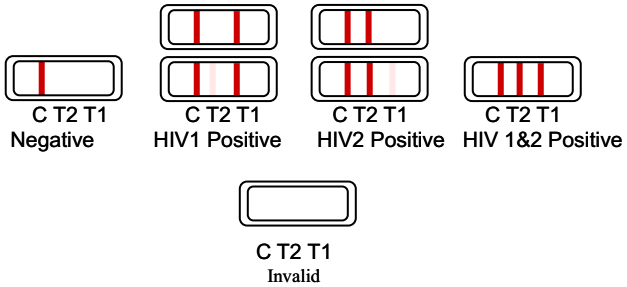
PROCEDURE

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 30 minutes. Do not interpret test result after 30 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 ºC. I f your room



temperature is significantly lower than 15 ºC, then the interpretation time should be properly increased.



INTERPRETATIO N OF RESULTS

- **Negative:** Only one colored band appears on the control (C)) region. No apparent band on the test (T2 and T1) region.
- **HIV 1Positive:** In addition to a pink colored control C band,a distinct darker pink colored band will appear in the test T1 region. A light pink color band might appear in the T2 region.
- **HIV 2 Positive:** In addition to a pink colored control (C) band, a distinct darker pink colored band will appear in the test T2) region. A light pink color band might appear in the T1 region.
- **Both HIV 1 and 2 positive:** In addition to a pink colored control (C) line, a distinct pink colored band will appear in both of the T1 and T2 region at the same time.
- **Invalid:** A total absence of color in both regions or no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration.

Limitations of the Test

Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of HIV infection can only be made on clinical grounds, if an individual meets the case definition for HIV infection 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 HIV infection even if the antibodies against HIV-1/HIV-2 are present in patient specimen. A negative result at any time does not preclude the possibility of HIV-1 / HIV-2 infection.
The HIV 1/ 2 rapid test is only used for the HIV antibodies screening test, the final diagnosis of HIV infection should be definite by the confirmation test.

Performance Characteristics

No standards for performance have yet been established for HIV rapid assays. The 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 IND HIV-1/HIV-2 as positive. No cross reactivity or interference was detected from other antigens, lipemic, or icteric samples.

Clinical Trials:

To establish the sensitivity and specificity of IND Diagnostics Anti-HIV(1+2) Whole Blood/Serum/Plasma test kit, 505 clinic samples were studied. Another commercially available qualitative test kit was used to compare with IND Diagnostic Anti-HIV whole blood/serum test kit for relative sensitivity and specificity in 505 samples. Only 3 samples were discordant. In turn, the agreement is 99.4%. The results are shown in Table 1.

Comparison of Anti-HIV 505 cases

		Results of IND kits		Subtotal
		+	-	
Results of Commercial kits	+	78	1	79
	-	2	424	426
Subtotal		80	425	505

Clinical Specificity:

Clinical Specificity is defined as the probability of a negative result in the absence of the particular condition. Clinical Specificity was determined by assaying blind-coded Anti-HIV negative samples. We classified as negative a sample that when tested with the IND Diagnostic Anti-HIV whole blood / serum Test showed only one colored band on Control Region.

Clinical Specificity = TN | (TN+FP), where TN: True Negative, and FP: False Positive
Clinical Specifl city = 424 | (424+2) = 99.5%

Clinical Sensitivity:

Clinical Sensitivlty is defined as the probability of a positive result in the presence of the particular condition. Clinical Sensitivlty was determined by Assaying blind-coded Anti-HIV positive samples. We classified as Positive a sample that when tested with the IND Diagnostic Anti-HIV whole blood / serum Test showed only one colored band on the Control Region and one color band on the Test Region 1 and/or one color band on the Test Region 2.
Clinical sensitivlty = TP | (TP+FN), where TP: True Positive, FN: False Negative
Clinical Sensitivlty = 78 | (78+1) = 98.7%

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