

IX - Limitations (Cont.)

The HIV 1/2 TEST is designed to detect antibodies to HIV 1/2 in serum, plasma and whole blood and thus is useful in screening blood and plasma donated for transfusion and further manufacture, in establishing prior infection of HIV 1/2 or in evaluating patients with AIDS symptoms and signs.

For repeatedly reactive specimens, it is recommended that more specific supplemental tests should be done and clinical evaluation on patient's situation should be performed before final diagnosis is made. Rapid testing alone cannot be used to diagnose AIDS even if the antibodies against HIV 1/2 are present in patient's serum, plasma or whole blood. A negative test result at any time does not preclude the possibility of exposure to or infection with HIV 1/2.

X - Performance Data

There is no recognized standard for establishing the presence or absence of HIV 1/2 antibodies in human blood samples. The only way to evaluate a new product is to perform different tests with commercially available panels of serum and to study the results of big comparative clinical trials. The HIV 1/2 TEST has been tested with a panel of 450 positive and negative sera by a reputable laboratory and showed **100% specificity and 100% sensitivity, even on diluted samples**. An example of an in-house study is shown in the following table.

Sample	# Pos.	Test Pos.	Test Neg.	Perf. (%)
HIV 1	120	120	0	100
HIV 2	8	8	0	100
NEG	100	0	100	100
NEG (RF+)	10	0	10	100
NEG (Syph+)	30	0	30	100
TOTAL	268	128	140	-

Note: This table reflects in-house testing panels.

Bibliography

1. Gallo, R.C., et al. 1984. Frequent detection and isolation of cytopathic retrovirus (HTLV-III) from patients with AIDS and at risk for AIDS. Science 224 (4648) : 500-503.
2. Schubach, J.M., et al. 1984. Serologic analysis of a subgroup of human T-lymphotropic retroviruses (HTLV-III) associated with AIDS. Science 224 : 505-507.
3. 1985. Provisional public health service inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome. MNWR 34 : 1-5.

Test Procedure

HIV 1/2 TEST

(Rapid)

For the detection of antibodies to HIV 1/2 in human serum, plasma or blood

I - Summary and Explanation

AIDS is characterised by changes in the population of T-cell Lymphocytes. In the infected individual, the virus causes a depletion of a sub-population of T-cells, called T helper cells which leaves these patients susceptible to opportunistic infections and some malignancies. The presence of the virus in the patient causes the immune system to elicit the production of anti-HIV 1 and/or HIV 2 antibodies.

Tests to detect these anti-HIV 1 or HIV 2 antibodies are now widely used in order to identify infected patients and/or the screening of blood derived products. Besides the ELISA test, many rapid immunofiltration tests are currently used for HIV 1/2 antibody detection. The HIV 1/2 TEST belongs to a new generation of rapid tests and is one of the most simple and easy to use tests currently on the market.

II - Principle

The HIV 1/2 TEST is a rapid immunochromatographic screening test for the detection of antibodies to HIV 1/2. It can be used with plasma, serum or whole blood.

The method employs a unique combination of anti-human immunoglobulin polyclonal antibodies, dye conjugate and viral proteins as antigen bound to the membrane solid phase. The multiple epitope fusion HIV 1/2 proteins are produced synthetically according to the genetic information of the virus. This material is therefore 100% non-infectious.

As the test samples flow through the absorbent device, the anti-human immunoglobulin-dye conjugate binds to the human immunoglobulins. Then, if the sample contains any antibodies to HIV 1/2, this mixture binds to the viral proteins of the solid phase in the positive reaction zone producing a pink-rose colour band. In the absence of anti-HIV 1/2 antibodies, there is no line in the positive reaction zone. The liquid continues flowing through the absorbent device and produces a pink-rose colour band in the control zone, demonstrating that the reagents are functioning correctly.

III - Test Kit Components

Each 10 or 20 test kit contains the following :

- HIV 1/2 TEST CARDS
- Sample capillaries
- Diluent bottle
- Instruction leaflet

IV - Storage and Stability

- The HIV 1/2 TEST is to be stored at any temperature between 4-37°C in the sealed pouch.
- Do not freeze the test kit.
- The stability of the HIV 1/2 TEST kit is 18 months under above mentioned storage conditions.

V - Precautions

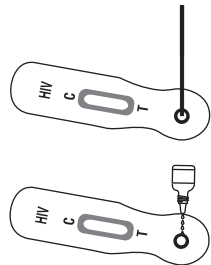
- This test is designed for "IN VITRO" use only.
- Do not pipette any of the material by mouth. Do not smoke, eat or drink in areas where specimens or kit reagents are handled.
- Use disposable gloves while handling all material of the kit or samples and performing the assay.
- Treat all materials used in the test as if they were infectious. Autoclave all materials for 1 hour at 121.5°C. Add sodium hypochlorite to liquid waste in order to reach a final concentration of 0.5 to 1%.
- Do not use beyond expiration date which appears on the package label.

VI - Specimen Collection

The HIV 1/2 TEST can be performed on serum, plasma or whole blood. Patient samples are best performed if tested immediately. Specimens should be refrigerated immediately at 2-8°C following collection up to 3 days. If the testing within 3 days is not possible, the specimens should be frozen (-20°C). If specimens have to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents.

VII - Assay Procedure

1. Remove the desired number of test cassettes from their protective wrapper.
2. Label the test cassettes with patient's name or identification number.
3. If using **whole blood** sample - swab, then prick patients finger. Fill the capillary with blood (10µl).
4. Using the capillary, add the entire contents into the well - as per drawing.
5. If using **serum or plasma** samples, use half (5µl) of the contents of capillary and add sample to the well.
6. Add 5 drops (+/- 250µl) of diluent using the dropper bottle into the well - as per drawing.
7. Read results of the test at 15 minutes after adding the diluent. Tests should **not** be read after 30 minutes as this sometimes leads to misinterpretation of results.



VIII - Interpretation of Results

Negative:

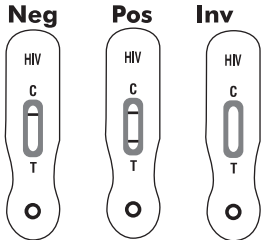
ONE distinct pink line in the upper part of the window.

Positive:

TWO distinct pink lines - one in the test zone area (lower part of window) and another in the control zone (upper part of window)

Inconclusive:

If there is no distinct pink coloured band visible both in the test zone and control zone, the test is inconclusive. It is recommended, in this case, to repeat the test with a new device.



IX - Limitations

The HIV 1/2 TEST procedure and the interpretation of results must be followed closely. This assay is designed for testing antibodies against HIV 1/2 in human serum, plasma and whole blood. Any result derived from the test of other body fluids and from a test of pooled serum, plasma or blood may not be interpreted correctly based on the current criteria. So other body fluids and pooled samples are not recommended in this assay.