

HIV I&II BAND™



A ONE-STEP TEST FOR THE QUALITATIVE DETECTION OF THE HIV I/II ANTIBODY IN HUMAN BLOOD/SERUM/PLASMA

For in vitro diagnostic use only.

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INTENDED USE

The HIV I&II BAND test is a rapid, one-step test for the qualitative detection of the HIV I/II *antibody* in human blood, serum and plasma. This test is intended primarily as an initial screening test and reactive samples should be confirmed by a supplemental assay such as an ELISA test or Western Blot or RIBA blot assays.

PRINCIPLE MATERIALS USED IN THE TEST

The capture reagents are recombinant proteins gp-160/gp-41 of HIV-1, and gp-36 of HIV-2 (Test line). The labeling reagents are recombinant proteins gp-160 of HIV-1 and gp-36 of HIV-2.

PRINCIPLE OF THE TEST

The HIV I&II BAND test consists of a chromatographic absorbent membrane strip with immobilized recombinant HIV I/II antigen. T1: HIV-I; T2: HIV-II. The antibody in sample reacts with a colored conjugate antigen, which is pre-dried on the strip, and an antigen-antibody complex is formed when antibody is present in the sample. The mixture then moves upward and the immuno complex labeled with dye will be captured by the antigen immobilized on the membrane, then a color band can be seen in T lines.

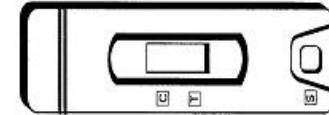
In the test procedure, the sample is added to the sample well with the aid of a dropper, and allowed to migrate through the absorbent device. The labeled antigen-dye conjugate binds to HIV antibody in the serum and migrates along the chromatographic membrane through capillary action. If there is *HIV antibody* present in the sample, a rose color band appears in the test window. In the absence of HIV antibody, there is no formation of a rose-pink color band in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the positive reaction zone to the control zone. Unbound conjugate binds to the reagents in the control zone, producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly.

MATERIALS PROVIDED

1. Test Devices.
2. Disposable pipettes. (packaged together in foil pouch)
3. A vial of reagent buffer.
4. Instructions for use.



PIPETTE



TEST DEVICE

STORAGE AND STABILITY

The test device may be stored at ambient temperature of 20 - 30°C (50-85°F) in the original unopened foil pouches. Each test unit contains a desiccant. The test should be used without delay once the pouch has been opened. In case the temperature of the test unit is considerably below room temperature and the humidity of the air is high, it is advisable to let the test unit reach room temperature before opening the pouch. The shelf life of test unit may be 18 months from the date of manufacture. The expiration date is printed on the pouch.

SAMPLE COLLECTION AND STORAGE

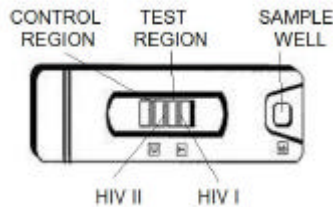
1. Collect the sample with a clean tube prefer . The sample for test prefer using the fresh morning samples.
2. For collect the blood sample, the anti-agglutinins reagent, such as EDTA, must be added in the collect tube.
3. If specimens are not immediately tested they should be refrigerated at 2-8°C for up to 2 days, or storage periods greater than 2 days, the sample can be stored at 2-20°C.

WARNINGS AND PRECAUTIONS

1. Wear disposable gloves while handling Specimens. Wash hands thoroughly afterwards.
2. Wipe up spills thoroughly using an appropriate intermediate to high-level disinfectant.
3. Decontaminate and autoclave all specimens, reaction Kits and any potentially contaminated materials.
4. Avoid splashing or aerosol formation.
5. Do not use the Kit after the expiration date.
6. For in vitro diagnostic use only.

TEST PROCEDURE

1. Remove the "Test Device" from its foil wrapper by tearing along the "splice" and place it on a clean level surface.



2. Fill the disposable dropper with the sample.
3. Hold the disposable dropper in a vertical position and apply 1 drops (~40 µl) of sample into the sample well of the test device.
4. Add one drop of Develop Buffer.
5. Read the results within 20 min.
6. The positive results will come out within a few min. But for confirm negative results, it should read at 20 min.

INTERPRETATION

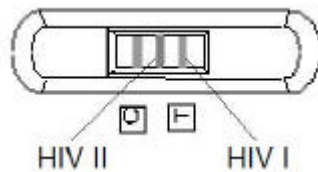
Positive Result: If there is a rose-pink color band in the control region (marked with a "C"), **and** a rosepink color band in the test region (marked with a "T"), *HIV antibody is present and the specimen is positive.*

T2: HIV-II located next to C line (~5 mm below C line)

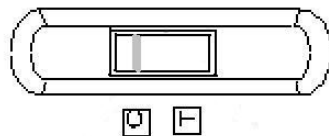
T2 line show up: HIV-II positive.

T1: HIV-I located next to T1 line (~10 mm below C line)

T1 line show up: HIV-I positive.



Negative Result: The absence of a color band in the test region next to the letter "T" indicates the absence of any detectable HIV antibody.



Invalid Result: If a color band does not appear in the control region "C", the test results are invalid. The sample may have been added to the wrong window, or the test device may have deteriorated. This specimen should be re-tested using a new test device.

Note: After performing the test, the result window ("T") should look clear white (negative result) or uniform line of rose pink (positive) at the end of 20 minutes. The test should not be considered as positive if the test zone shows irregular spots or other shape.

LIMITATIONS OF THE TEST

1. The HIV I&II BAND test is limited to the detection of HIV I/II antibody only. The clinical data has indicated that there is a cross reactivity between the two antigen HIV-I and HIV-II. So in some positive cases, both line, T1 and T2, might show up at a device.
2. Although the HIV I&II BAND is very accurate in detect HIV I/II antibody, a very low incidence of false results might occur.
3. If negative or questionable results are obtained, and the infection is suspected, the test should be repeated on a fresh serum specimen.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after evaluation of all clinical and laboratory findings.

External Controls:

Like any *in vitro* device, performance of HIV I/II antibody should be checked for accuracy and batch-to-batch variation by using known serum pools. These sera should be used in the same way as described in the assay procedure for serum samples. It is recommended that these control sera be used at least once with every batch or new shipment.

Internal Controls:

In addition to the external controls the test device has built-in controls. With each testing there should always be a rose-pink color band in the control region ("C"). If the color band does not appear in the control region, the result should be considered invalid. Also, after performing the test, the result window ("T") should look clear white or uniform light pink. If the result window shows large red or purple streaks at the end of 10 minutes, the test should be considered invalid. Repeat the test using a fresh test device.

SENSITIVITY

Sensitivity: 99 % Specificity: 99 %
The reference HIV -I and HIV -II calibrated by EIA are used as a quality control for the sensitivity of kits.

Assay method	Reference HIV-II Absorbency
AbbottHIVAB@	
HIV -I/II EIA Genetic Systems™	0.330
HIV -I/II EIA Genetic System™	0.447
HIV -II EIA	0.294

HIV I&II BAND	Time of T line show up 2-3 minutes

Assay Method	Reference HIV -I Absorbency
Abbot HIVAB HIV -I EIA Genetic System LAV EIA	0.319
	0.444

HIV I&II BAND	Time of T line show up 2-3 minutes

REFERENCES

1. Gall, R.C.J. AIDS, 30:380, 1990
2. Clavel, F. et. al. New Eng. J. Med. 316:1346-48, 1987
3. Gallo, R.C., et. al. Science 224:500-502, 1984

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