



**Human Immunodeficiency Virus  
Rapid Test Strip  
(Serum/Whole blood)**

A rapid test for the qualitative detection of antibodies to Human Immunodeficiency Virus-1 and/or 2 in serum or whole blood.

*For professional in vitro test use only.*

**INTENDED USE**

The *ABI* HIV 1/2 Test Device (Serum/Plasma/whole blood) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in serum or whole blood.

**SUMMARY**

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with a high potential risk for developing AIDS (1). HIV-2 has been isolated from West African AIDS patients and from sero-positive asymptomatic individuals (2). Both HIV-1 and -2 elicit an immune response (3). Detection of HIV antibodies in serum or plasma or whole blood is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV (4). Despite the differences in their biological characteristics, serological activities and genome sequences of HIV-1 and -2 show strong antigenic cross-reactivity (5, 6). Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

**PRINCIPLE**

The *ABI* HIV 1/2 Test Device (Serum/Plasma/whole blood) is a qualitative, membrane based immunoassay for the detection of antibody to HIV in serum or plasma or whole blood. The membrane is coated with recombinant HIV antigens on the test area of the device. When a serum or plasma or whole blood specimen is applied to the Sample Well of plastic device, it reacts with recombinant antigen coated colored particle. The mixture then migrates towards the Result Window of device and reacts with the recombinant HIV antigens on the membrane in the test area. If the specimen contains antibodies to HIV-1 or HIV-2, the colored line will appear in the test area, showing a positive result. The absence of the colored line indicates that the specimen does not contain the anti-HIV antibodies, showing a negative result. A colored line will always appear at the control area if the test has been performed properly.

**REAGENTS**

The test device contains recombinant antigen coated colored particle and recombinant antigens coated on the membrane.

**PRECAUTIONS**

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at 4-30 °C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

- The *ABI* HIV 1/2 Test Device (Serum/Plasma/whole blood) can be performed using either serum or plasma or whole blood.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis when serum or plasma is used. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. The plasma or serum may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

**PROCEDURE**

**Materials Provided**

- Test devices
- Developer solution
- Package insert

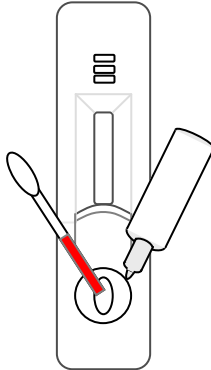
**Materials Required But Not Provided**

- Specimen collection container
- Disposable specimen droppers
- Timer

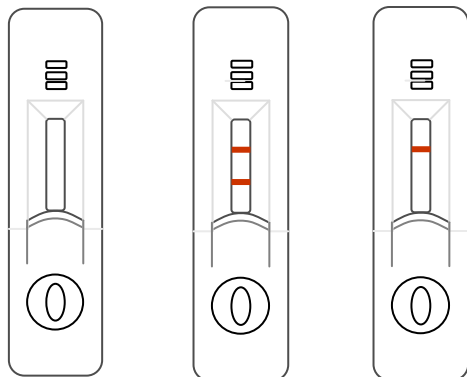
## DIRECTIONS FOR USE

Allow test device, developer solution, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing. Use a new pipette for each sample/test.

1. Remove the test device from the foil pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Add 10  $\mu$ l of serum or plasma, or 20  $\mu$ l of whole blood to the sample well of the test device, then add two (2) full drops of developer solution to the sample well of the device and start the timer.
3. The test result should be read at 10 minutes.



## INTERPRETATION OF RESULTS



Invalid

Positive

Negative

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**NEGATIVE:** A color band will appear in the control area, which indicates a negative result.

**POSITIVE:** Two bands will appear in the control and test areas, which indicate a positive result for HIV-1or/and HIV-2, respectively.

Note: Low titers of anti-HIV 1/2 antibodies might result in a faint line appearing in the test region after a prolonged time.

**NOTE:** The intensity of the red color in the test area will vary depending on the concentration of anti-HIV 1/2 antibodies present in the specimen. However, neither the quantitative value nor the rate of increase in anti-HIV 1/2 antibodies can be determined by this qualitative test.

## QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control area is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

## LIMITATIONS

1. The *ABI* HIV 1/2 Test Device is for *in vitro* use only. The test should be used for the detection of antibodies to HIV in specimen.
2. The *ABI* HIV 1/2 Test Device will only indicate the presence of antibodies to HIV in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1 and/or -2 infection.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or western blot analysis. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of HIV -1 and/or -2 infection.

## EXPECTED VALUES

The *ABI* HIV 1/2 Test Device has been compared with a leading commercial HIV EIA test. The correlation between these two systems is 99%.

## PERFORMANCE CHARACTERISTICS

### Accuracy

The *ABI* HIV 1/2 Test Device has passed Anti-HIV1 Low Titer Performance Panel (PRB106), Anti-HIV1 Seroconversion Panel J (PRB910), and Anti-HIV-2 Performance Panel (PRF 202) (Boston Biomedica, Inc.), and has also been compared with leading commercial HIV EIA test using clinical specimens.

The recombinant antigens used in the *ABI* HIV 1/2 Test Device are encoded by genes for the glycoproteins on the viral envelope. The *ABI* HIV 1/2 Test Device is highly specific for anti-HIV-1 and anti-HIV -2 antibodies compared to a leading commercial HIV EIA test.

	HIV EIA		Total
	Positive	Negative	
ABI Positive	238	2	240
ABI Negative	0	436	436
Total	238	438	676

Relative Sensitivity: 100%

Relative Specificity: 99.5%

**Precision: Intra-Assay**

Within-run precision has been determined by using 20 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 100% of the time.

**Precision: Inter-Assay**

Between-run precision has been determined by 20 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the ABI HIV 1/2 Test Device have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 100% of the time.

**BIBLIOGRAPHY**

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