HIV 1.2 Ab FIA Rapid Test Device
(Whole Blood/Serum/Plasma)
FI2-HIV-001

A qualitative rapid test for the detection of HIV 1.2 antibodies (HIV 1.2) in whole blood, serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE
The HIV 1.2 Ab FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative detection of HIV 1.2 antibodies (HIV 1.2) in whole blood, serum or plasma.

SUMMARY
Acquired Immunodeficiency Syndrome (AIDS) is thought to be caused by at least two retroviruses, HIV-1 and HIV-2. HIV-1 and HIV-2 are similar in genomic structure, morphology and ability to cause AIDS.[1] HIV is transmitted mainly by sexual contact, exposure to blood or blood products (including sharing contaminated needles and syringes), or from an infected mother to her foetus. People with increased risk of HIV infection include hemophiliacs, intravenous drug-users and men having sex with men (MSM). Serological evidence of HIV infection may be obtained by testing for HIV antigens or antibodies. Antigen can generally be detected during the acute phase and during the symptomatic phase of AIDS only. Antibodies to HIV can be detected throughout virtually the total infection period, starting at or shortly after the acute phase and lasting until the end stage of AIDS. Therefore, the use of highly sensitive antibody assays is the primary approach for diagnosis of HIV infection.[2]
The HIV 1.2 Ab FIA Rapid Test Device can be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection. Using a HIV test provides an opportunity to identify more individuals who are unaware they are living with HIV. HIV testing provides results during the initial visit allowing for immediate counselling and follow-up opportunities.

PRINCIPLE
The HIV 1.2 Ab FIA Rapid Test Device detects HIV 1.2 antibodies based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains HIV 1.2 antibodies, it attaches to the fluorescent microspheres-conjugated HIV 1.2 recombinant proteins. Then the complex will be captured by the HIV1 and HIV2 recombinant proteins in test line region. The concentration of HIV 1.2 antibodies in the sample correlates with the fluorescence signal intensity captured on the T line, which can be read by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). The test results of the HIV 1.2 Ab FIA Rapid Test will be displayed on the Fluorescence Immunoassay Device screen.

REAGENTS
The test contains HIV 1.2 recombinant proteins conjugated fluorescent microspheres and HIV1 and HIV2 recombinant proteins coated on the nitrocellulose membrane.

PRECAUTIONS
1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda HIV 1.2 Ab FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device by approved medical professionals.

STORAGE AND STABILITY
1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS
- 25 x foil wrapped HIV 1.2 Ab test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (HIV 1.2)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION
For Venipuncture Specimens
1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K2 can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum specimens.

DIRECTIONS FOR USE
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 15 minutes. *Quick* Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. **Whole Blood/Serum/Plasma:** Transfer **20 µl of whole blood, serum, or plasma** into the buffer tube, mix the specimen and the buffer well.
5. **Add diluted specimen with a Pipette**: Pipette **75 µl** of diluted specimen into the sample well of the test device. Start the timer at the same time.
6. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS
The result of tests for HIV 1.2 is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Value. Value is calculated that a measured signal is divided by an appropriate cutoff value.

- Test results of a Value ≥ 1.00 are considered positive for HIV1/2.
- Test results of a Value < 1.00 are considered negative for HIV1/2.

QUALITY CONTROL

Each Biopanda HIV 1.2 Ab FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The HIV 1.2 Ab FIA Rapid Test Device is for *in vitro* diagnostic use only. The test should be used for the detection of HIV 1.2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV antibodies can be determined by this qualitative test.
2. Failure to follow the test procedure or improper sample collection may adversely affect test performance or invalidate the test result.
3. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
4. A negative test result may occur if the level of antibody in a sample is below the detection limit of the test or if the sample was collected, transported, or stored improperly.
5. Reactive test results should be confirmed by additional testing using other tests.
6. A person who has HIV-1 p24 antigen or antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus. However, a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.
7. This assay has not been evaluated for newborn screening, cold blood specimens, or individuals less than 12 years of age.
8. Specimens from individuals with Toxoplasma IgG, human anti-mouse antibodies, rheumatoid factor, elevated triglycerides (above 600 mg/dL), herpes simplex virus infection, hospitalized and cancer patients may give false positive test results.
9. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.

PERFORMANCE CHARACTERISTICS

The HIV 1.2 Ab FIA Rapid Test Device has been evaluated with a leading commercial HIV 1.2 EIA using clinical specimens for HIV 1.2. The results show that the sensitivity of the HIV 1.2 FIA Rapid Test Device is 96.8% and the specificity is 97.8% relative to the EIA, the correlation between these two systems is 97.5%.

Method		ELISA		Total Results
HIV 1.2 FIA Rapid Test Device	Results	Positive	Negative	
	Positive	60	3	63
	Negative	2	135	137
Total results		62	138	200

Relative sensitivity: 96.8% (95%CI*: 88.8%~99.6%);
Relative specificity: 97.8% (95%CI*: 93.7%~99.5%);
Accuracy: 97.5% (95%CI*: 94.3%~99.2%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of 3 specimens: a negative, low positive and high positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same 3 specimens: a negative, low positive and high positive. Three different lots of HIV 1.2 Ab FIA Rapid Test Device have been tested over a 3-days period using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HIV 1.2 Ab FIA Rapid Test Device has been tested by HAMA, RF, HBsAb, HBeAb, HBcAb, Syphilis, HIV, HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HIV1/2 specimens.

Ascorbic Acid: 200 mg/dL	Bilirubin: 500 mg/dL
Creatin: 200 mg/dL	Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL	Hemoglobin: 1000 mg/dL
Albumin: 2000 mg/dL	Oxalic Acid: 600 mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCES

1. Guyader, M., Emerman, M., Sonigo, P., et al. Genome organization and transactivation of the human immunodeficiency virus type 2. Nature 326:662-669, 1987.
2. Kenealy, W., Reed, D., Cybulsky, R., et.al. (1987) Analysis of human serum antibodies to human immunodeficiency virus (HIV) using recombinant ENV and GAG antigens. AIDS Research and Human Retroviruses 3: 95-105.

Index of Symbols

	Manufacturer	Σ	Tests per kit	2	Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
4°C 30°C	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's HIV 1.2 Ab FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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