HIV p24 Ag FIA Rapid Test Device
(Whole Blood/Serum/Plasma)
FI2-P24-001

A qualitative rapid test for the detection of HIV p24 Antigen (HIV p24 Ag) 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 p24 Ag FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative detection of HIV p24 Antigen (HIV p24 Ag) in whole blood, serum or plasma.

SUMMARY
The HIV p24 antigen is a small piece of protein that is found on the capsule of the HIV virus. When a person is infected with HIV, these bits of protein can be found floating in the blood. The HIV p24 antigen test is the test that detects these bits of protein. This test was first developed as a HIV screening test but rapidly ran out of favour due to the development of more advanced NAT tests.[1] The window period for p24 testing is also very small. This test alone is only accurate for between 3 and 6 weeks post exposure.[2] So it is a test with very limited applications unless combined with HIV antibody test. The presence of p24 antigen in the blood indicated a recent HIV infection.[3]
The HIV p24 Ag FIA Rapid Test Device is a test to qualitatively detect the presence of p24 antigen of HIV 1 in human whole blood, serum or plasma specimen. The test utilizes latex conjugate HIV p24 antibody to selectively detect p24 antigen of the HIV type 1 in whole blood, serum or plasma.

PRINCIPLE
The HIV p24 Ag FIA Rapid Test Device detects p24 antigen of Human Immunodeficiency Virus (HIV) type 1 based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains p24 antigen, it attaches to the fluorescent microspheres-conjugated p24 antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of HIV p24 antigen 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 P24 AG FIA Rapid Test will be displayed on the Fluorescence Immunoassay Device screen.

REAGENTS
The test contains HIV antibody coated particles and HIV antibody coated on the 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 p24 Ag 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 p24 Ag test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (HIV p24 Ag)
- 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, Heparin sodium, Sodium Citrate and Potassium Oxalate 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 p24 Ag 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 HIV antigen.
- Test results of a Value < 1.00 are considered negative for HIV antigen.

QUALITY CONTROL

Each Biopanda HIV p24 Ag 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 p24 Ag FIA Rapid Test Device is for *in vitro* diagnostic use only. The test should be used for the detection of HIV antigen in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV p24 antigens can be determined by this qualitative test.
2. The HIV p24 Ag FIA Rapid Test Device will only indicate the presence of HIV p24 antigens in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. 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 testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HIV infection.

PERFORMANCE CHARACTERISTICS

The HIV p24 Ag FIA Rapid Test Device has been evaluated with a leading commercial HIV p24 Ag EIA using clinical specimens for HIV p24 Ag. The results show that the sensitivity of the HIV p24 Ag 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 p24 Ag FIA Rapid Test Device	Results	Positive	Negative	
	Positive	32	1	33
	Negative	1	359	360
Total results		33	360	393

Relative sensitivity: 96.97% (95%CI*: 84.24%~99.92%);
Relative specificity: 99.72% (95%CI*:98.46%~99.99%);
Accuracy: 99.49% (95%CI*:98.17%~99.94%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of 4 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 4 specimens: a negative, low positive and high positive. Three different lots of HIV p24 Ag 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 p24 Ag FIA Rapid Test Device has been tested by Anti-HAMA IgG, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HCV IgG, anti-Syphilis IgG, anti-RF IgG, anti-MONO IgM, anti-*H. Pylori* IgG, anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-Toxo IgG, anti-Toxo IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

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

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1.1 g/dL
Bilirubin: 1g/dL	Oxalic Acid: 600 mg/dL

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

REFERENCES

1. Blacklist of English teachers suspected of having AIDS pursued." This image of Randall L. Tobias is used in a Korean news article suggesting that foreign English teachers residing in Korea are at risk for AIDS. Accessed 16 Feb., 2010.
2. Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood". US Food and Drug Administration. Retrieved 12 October2013.
3. FDA Approves First Nucleic Acid Test (NAT) Systems to Screen Plasma for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)

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 p24 Ag FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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