AFP FIA Rapid Test Device

(Serum/Plasma)

FI2-AFP-001

A rapid test for detecting Alpha-Fetoprotein (AFP) in 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 Biopanda AFP FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Alpha-Fetoprotein (AFP) in serum or plasma.

SUMMARY

Alpha-Fetoprotein (AFP) is normally produced during foetal and neonatal development by the liver, yolk sac and in small concentrations by the gastrointestinal tract.[1] By the second year of life, AFP concentrations decrease rapidly, and thereafter only trace amounts are normally detected in serum.[2] In general, normal adults have serum AFP concentrations of less than 10ng/ml.[3] Elevated AFP levels occur in several malignant diseases including hepatocellular carcinoma, testicular nonseminomatous origin, and occasionally of other entodermal origin.[4] AFP has also been used to detect early tumours in people at high risk for liver cancer. Studies of patients with large hepatic metastases or viral hepatitis also indicate slightly elevated or persistent AFP values.[5] In areas where liver cancer is common, the use of AFP tests for screening has resulted in the detection of many tumours at an earlier stage.[6] Detection of elevated AFP levels can also be used in the detection of foetal open neural tube defects.[7]

PRINCIPLE

The AFP FIA Rapid Test Device detects AFP based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains AFP, it attaches to the AFP fluorescent microspheres-conjugated anti-AFP antibodies. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane. The concentration of AFP in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of AFP in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) to show AFP concentration in specimen.

REAGENTS

The test kit includes anti-AFP antibody coated fluorophores and anti-AFP 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 AFP 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 AFP Rapid Test Device
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (AFP)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

BLOOD SAMPLE TAKING

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 1 day, for long term storage, specimens should be kept below -20°C.
3. 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.
4. EDTA and Heparin sodium, can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Transfer **50 µL of serum or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours.

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.
Allow the test, 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. **Serum/plasma**: Transfer 50 µl of serum/plasma into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette**: Pipette 75 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.

“Quick test” mode: Insert the test device into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.
“Standard test” mode: Insert the test device into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for AFP 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.

Linearity range of the Biopanda AFP FIA Rapid Test Device is 5-400 ng/ml. Reference range: <20 ng/ml.

QUALITY CONTROL

Each Biopanda AFP 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. 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 Biopanda AFP FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of AFP.
2. The Biopanda AFP FIA Rapid Test Device will only indicate the presence of AFP antigen in the specimen and should not be used as the sole criterion for the diagnosis of Hepatocellular Carcinoma or foetal open neural tube defects.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of the Biopanda AFP FIA Rapid Tests are based on measuring the levels of AFP in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
<20 ng/ml	Healthy
≥20 ng/ml	Risk of hepatocellular carcinoma

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **DETECTION RANGE**: 5-400 ng/ml.
3. **LINEARITY RANGE**: 5-400 ng/ml, R≥0.990
4. **PRECISION**

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens containing 10 ng/ml and 20 ng/ml of AFP. C.V. is ≤ 15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 10 ng/ml and 20 ng/ml of AFP. C.V. is ≤ 15%.

INTERFERING SUBSTANCES

The following substances do not interfere with the test results at the indicated concentrations: Ascorbic Acid at 200 mg/l, Hemoglobin at 10 g/l, Triglyceride at 30 g/l, Bilirubin at 1,000 mg/dl, Uric Acid at 200 mg/l.

METHOD COMPARISON

The assay was compared with Abbott AFP reagent kit with 100 samples. The correlation coefficient(r) is 0.981.

REFERENCES

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3. Davids, Jacobs, et al. *Laboratory test handbook*, Lexi-Comp Inc, 1996, 4th Edition: 73.
4. Abelev GI. Alpha-fetoprotein in ontogenesis and its association with malignant tumors. Adv. *Cancer Res*. 14: 295-358, 1971.
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6. Nasser J. The Role of Biologic Tumor Markers in Testicular Cancer. *Cancer*. 45(7):1755-1761,1980.
7. Bock J. Current Issues in Maternal Serum Alpha-Fetoprotein Screening. *Clinical Chemistry*. 97(4)541-554, 1992.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
	*In vitro* diagnostic medical device		Expiration date		Catalogue number
	Storage temperature		Lot Number		Consult instructions for use
	Do not use if package is damaged				

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

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Revision date: 31/03/2025