Prolactin FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-PLC-001

A rapid test for detecting prolactin 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 Biopanda Prolactin FIA Rapid Test Device is intended for *in vitro* quantitative determination of human Prolactin (PRL) in whole blood, serum or plasma as an aid in the diagnosis of prolactinoma, as well as the cause of menstrual irregularities in women and erectile dysfunction in men.

SUMMARY

Prolactin, also known as lactotropin, is a protein best known for its role in enabling mammals and birds, usually females, to produce milk. It is influential in over 300 separate processes in various vertebrates, including humans.[1] Prolactin is secreted from the pituitary gland in response to eating, mating, oestrogen treatment, ovulation and nursing. It is secreted heavily in pulses in between these events. Prolactin plays an essential role in metabolism, regulation of the immune system and pancreatic development. In usual circumstances, in the absence of galactorrhea, lactation ceases within one or two weeks following the end of breastfeeding. Hypersecretion is more common than hyposecretion. Hyperprolactinemia is the most frequent symptom of the pituitary gland tumours, termed prolactinomas. Prolactin levels may be checked as part of a sex hormone workup, as elevated prolactin secretion can suppress the secretion of follicle stimulating hormone and gonadotropin.

PRINCIPLE

The Biopanda Prolactin FIA Rapid Test Device detects Prolactin based on Fluorescence Immunoassay. The sample moves through the strip from the sample pad to the absorbent pad. If the specimen contains PRL, it attaches to fluorescent microspheres conjugated to anti-PRL antibodies. Any complexes will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of PRL in the sample correlates linearly with the intensity of the fluorescence signal captured on the T line. By measuring the signal intensity of the test against a standard curve, the concentration of PRL in the sample can be calculated by the Device to show the PRL concentration in the specimen.

REAGENTS

The test kit includes anti-PRL antibody coated fluorophores and anti-PRL antibody coated on the test strip 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 Prolactin FIA Rapid Test 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 Prolactin test Devices
- 25 x Specimen collection tubes with buffer solution
- 1 x ID card (Prolactin)
- 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, ensure sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can affect test results.
2. Take a tube with buffer solution out of the kit. Document patient's name or ID on it.

BLOOD SAMPLE COLLECTION

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. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within half-day of collection. Do not freeze whole blood specimens. Whole blood collected by finger prick should be tested immediately.
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 K2 and Sodium citrate can be used as the anticoagulant agent for collecting the specimen.

SAMPLE PREPARATION

1. The specimen (75 µl of whole blood, serum or plasma) can be added directly by micro pipette into the buffer.
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 rest for approximately 1 minute.
4. The sample can then be used immediately or stored at 2-8°C 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. Select the sample type used: "Serum/plasma" or "Whole Blood".
4. Remove the test Device from the sealed foil pouch and place it on a clean, level surface. The Device should be used within one hour but best results will be obtained if the test is performed immediately after opening the foil pouch.
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. 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 concentration of Prolactin will be displayed on the screen of the Biopanda Fluorescence Immunoassay Device. The analyser will provide the result in **ng/ml**. To convert this result to **mIU/L**, multiply by a factor of **21.2**

The linearity range of the Prolactin FIA Rapid Test is 1.0–200 ng/ml.

QUALITY CONTROL

Each Prolactin 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 "N/A" message on the Analyser. 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 Prolactin FIA Rapid Test Device is for professional *in vitro* diagnostic use and should only be used for the quantitative detection of Prolactin.
2. The Biopanda Prolactin FIA Rapid Test Device will only indicate the presence of Prolactin antigen in the specimen and should not be used as the sole criterion for diagnosing prolactinoma.
3. As with all diagnostic tests, a final diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of Prolactin may produce a dose hook effect, resulting in incorrect interpretation of Prolactin levels. A dose hook effect has not been observed in up to 400 ng/ml of PRL.
5. The assay range of this test is 1.0–200 ng/ml. If the concentration of PRL in the sample exceeds this range, the sample should be diluted with calf or a negative human serum sample and the sample re-tested. The sample should not be diluted by more than a factor of 4. Ensure the dilution factor is accounted for when calculating the final concentration of PRL.
6. The results of the Biopanda Prolactin FIA Tests are based on measuring the levels of Prolactin in a specimen. It should not be used as the sole criterion for treatment decisions.

EXPECTED RESULTS

Gender	Condition	Reference range	
		ng/ml	mIU/L
Female	Not pregnant	2~25	42.4~530
	Pregnant	10~209	212~4430
Male	N/A	2~18	42.4~381.6

Note: The expected results provided above are for reference purposes only. It is recommended that each laboratory establish an actual reference interval based on the population, age, gender, diet, etc. in their region.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **ANALYTICAL SENSITIVITY**: The Biopanda Prolactin FIA Test Device can detect levels of Prolactin as low as 1 ng/ml in whole blood, serum or plasma.
3. **LINEARITY RANGE**: 1–200 ng/ml, R≥0.990
4. **PRECISION**

   INTRA-LOT PRECISION

   Within-run precision has been determined by using 10 replicates of 2 specimens containing 5 ng/ml and 150 ng/ml of PRL. CV(%) is ≤15%.

   INTER-LOT PRECISION

   Between-run precision has been determined by using 10 replicates of 2 specimens on three different lots of test. CV(%) is ≤15%.
5. **METHOD COMPARISON**

The assay was evaluated on 78 clinical specimens and compared against a commercially available Prolactin test kit. The correlation coefficient(r) is 0.951

REFERENCES

1. Bole-Feysot C, Goffin V, Edery M, Binart N, Kelly PA (June 1998). "Prolactin (PRL) and its receptor: actions, signal transduction pathways and phenotypes observed in PRL receptor knockout mice". Endocrine Reviews. 19 (3): 225–68. doi:10.1210/edrv.19.3.0334. PMID 9626554.

SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test	IVD	*in vitro* diagnostic medical device
	Consult instructions for use	LOT	Batch code
	Storage temperature		Contains sufficient for <*n*> tests
REF	Catalogue number		Do not use if package is damaged

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

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