



Cortisol FIA Rapid Test Device (Serum/Plasma)

Catalogue Number: FI2-COR-001

A Fluorescence Immunoassay for the quantitative detection of cortisol in human serum or plasma using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

For professional *in vitro* diagnostic use only.

INTENDED USE

The Biopanda Cortisol FIA Rapid Test Device is based on fluorescence immunoassay for the quantitative determination of cortisol in human serum and plasma, with the use of the fluorescence immunoassay device (BR-FIA-2000). It is intended to be used as an aid in the diagnosis of related diseases with abnormal cortisol levels.

BACKGROUND

Cortisol is a steroid hormone, one of the glucocorticoids, made in the cortex of the adrenal glands and then released into the blood, which transports it all round the body. Almost every cell contains receptors for cortisol and so cortisol can have lots of different actions depending on which sort of cells it is acting upon. These effects include controlling the body's blood sugar levels and thus regulating metabolism, acting as an anti-inflammatory, influencing memory formation, controlling salt and water balance, influencing blood pressure and helping development of the foetus. In many species, cortisol is also responsible for triggering the processes involved in giving birth.

A similar version of this hormone, known as corticosterone, is produced by rodents, birds and reptiles.

TEST PRINCIPLE

The Biopanda Cortisol FIA Rapid Test Device detects cortisol based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. The cortisol in the sample will compete with the cortisol antigen coated on the membrane. The less cortisol in the sample, the more chance that fluorescent microspheres-conjugated anti-cortisol antibodies can be captured by the cortisol antigen coated on the membrane (test line). The concentration of cortisol in the sample is inversely related to the intensity of the fluorescent signal captured on the test line. According to the fluorescence intensity of the test and the standard curve, the concentration of cortisol in the sample can be calculated by analyser to show cortisol concentration in sample.

REAGENTS

The test includes anti-cortisol antibody coated fluorophore and Cortisol-BSA 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 samples by using a new sample collection container for each sample obtained.
4. Do not eat, drink or smoke in the area where the samples and tests are handled. Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of samples.
5. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when samples are assayed.
6. Do not interchange or mix reagents or ID cards from different lots.
7. Extremes in humidity and temperatures can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda Cortisol FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device by medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the 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 CONTENTS

Provided:

- 25 x Foil wrapped cortisol test devices
- 25 x Sample collection tubes with buffer solution
- 1 x ID card (COR)
- 1 x Package insert

Required but not provided:

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

SAMPLE COLLECTION AND PREPARATION

- Collect the samples according to standard procedures. Only use clear, non-haemolysed samples.
- Do not leave samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2-8°C for up to 3 days. For long term storage, samples should be kept below -20°C.
- Bring samples to room temperature (15-30°C) prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Avoid repeat freeze thaw cycles.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User Manual for the complete instructions on operating the device. 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 simultaneously.

Refer to the user manual for further information.

Allow the test device, specimen, and buffer tube to reach room temperature (15-30°C) prior to testing.

1. Turn on the analyzer and insert the ID card into the 'Code' port and wait for the 'ID card imported successfully' pop-up. Fill in the necessary details in the 'Test Info' section.
2. Remove the test device from the foil pouch and place it on a clean, level surface. Testing should start within an hour of opening the foil pouch.
3. Pipette **75 µL of serum or plasma** into the sample collection tube with buffer. Mix the sample and the buffer well using the pipette.
Note: the diluted sample should be used immediately. Do not store for longer than 4 hours at 2-8°C.
4. Pipette **75 µL of diluted sample** into the sample well of the test device.
5. Insert the test device into the analyzer test device slot. Then according to user requirements, select either 'Standard test' or 'Quick test' mode.
6. **Test results should be interpreted at 15 minutes** using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The test results are calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyzer screen after testing is complete. For additional information, please refer to the user manual.

The assay range is 50 nmol/L - 1000 nmol/L (1.8-36.2 µg/dL).

QUALITY CONTROL

Each Biopanda Cortisol 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 "N/A" message on the analyser. Insufficient sample 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.

REFERENCE INTERVAL

Normal Reference Range	140 - 690 nmol/L (blood sample taken at 8:00 am) 80 - 410 nmol/L (blood sample taken at 4:00 pm)
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Cortisol levels in the blood vary throughout the day, with levels highest in the morning and lowest at midnight.

Note: Due to differences in geography, race, environment, gender, etc., each laboratory should establish its own reference values.

PERFORMANCE CHARACTERISTICS

1. Method Comparison

The Biopanda Cortisol FIA Rapid Test Device was tested and compared with commercial cortisol devices on 78 clinical samples. The overall correlation coefficient (r) is 0.981.

2. Accuracy

The test deviation is $\leq \pm 15\%$.

3. Analytical sensitivity

The Biopanda Cortisol FIA Rapid Test Device can detect levels of cortisol as low as 50 nmol/L in serum and plasma.

4. Linearity Range

50 nmol/L - 1000 nmol/L, $R \geq 0.990$

5. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 samples containing 100 nmol/L and 500 nmol/L of Cortisol. C.V. is $\leq 15\%$.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 samples containing 100 nmol/L and 500 nmol/L of Cortisol. C.V. is $\leq 15\%$.

6. Interfering Substances

The following interfering substances have been tested using the Biopanda Cortisol FIA Rapid Test Device and no interference was observed.

Substance	Concentration
Estradiol	600 ng/mL
Estriol	500 ng/mL
Progesterone	600 ng/mL
Danazol	500 ng/mL
Testosterone	50 ng/mL
Haemoglobin	500 mg/mL
Bilirubin	1 g/mL

LIMITATIONS OF THE TEST

- The Biopanda Cortisol FIA Rapid Test Device should be used only with the analyser.
- The Biopanda Cortisol FIA Rapid Test Device is for professional *in vitro* diagnostic use and should only be used for the quantitative detection of cortisol. This test should not be used as the sole criteria for clinical diagnosis. If the result is abnormal, other clinical findings and alternative test methods are recommended to reach proper medical treatments.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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		<i>in vitro</i> diagnostic medical device
	Consult instructions for use		Batch code
	Storage temperature		Contains sufficient for <n> tests
	Catalogue number		Do not use if package is damaged

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



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