



# Cortisol FIA Rapid Test Cassette

Catalogue No.: FIA-COR-001

*For professional in vitro diagnostic use only.*

## INTENDED USE

The Biopanda Cortisol FIA Rapid Test Cassette is based on fluorescence immunoassay for the quantitative determination of cortisol in human serum and plasma, with the use of the fluorescence immunoassay analyser. 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 Cassette 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 T 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. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
5. Do not interchange or mix reagents or ID cards 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 Cortisol FIA Rapid Test Cassette should only be used with the Biopanda Fluorescence Immunoassay Analyser by 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

### Materials Provided:

- 10 x foil wrapped cortisol test cassettes
- 10 x Sample collection tubes with buffer solution
- 1 x ID card (COR)
- Package Insert

### Materials required but not provided:

- Timer
- Pipette
- Sample collection containers
- Centrifuge
- Biopanda Fluorescence Immunoassay Analyser

## 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 Analyser User Manual for the complete instructions on use of the analyser. The test should be conducted at room temperature.

**Allow the test, sample, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Turn on the Analyser.
  2. Take out the ID card and insert it into the ID Card Slot. Choose test mode and/or sample type according to needs.
  3. Remove the test cassette from the foil pouch and use within an hour of opening. For optimal results, perform test immediately after opening. Place the cassette on a level and clean surface.
  4. Pipette **75 µL of serum or plasma** into the sample collection tube with buffer. Mix the sample and the buffer well.
- Note: the diluted sample should be used immediately and stored for no more than 4 hours at 2-8°C.**
5. Pipette **75 µL of diluted sample** into the sample well of the cassette. Start the timer.
  6. Test results should be interpreted at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Analyser.

**Note:** There are different test modes for the Biopanda Fluorescence Immunoassay. The difference between them is incubation of the test cassette is outside or inside the analyser.

Choose test mode accordingly and confirm sample type. Consult the user manual of the analyser for detailed operation information.

Operator must consult the Biopanda Fluorescence Immunoassay Analyser User Manual prior to use and become familiar with the processes and quality control procedures.

## INTERPRETATION OF RESULTS

The result of the cortisol test is calculated by the Biopanda Fluorescence Immunoassay Analyser and displayed on the analyser screen. For additional information, please refer to the user manual.

The assay range of this Cortisol test is 50 nmol/L - 1000 nmol/L (1.8-36.2 µg/dL). The default result unit of this product is nmol/L, and the result can be converted to µg/dL by the following formula:

Test concentration in (nmol/L) / 27.6 = result concentration in (µg/dL)

## QUALITY CONTROL

Each Biopanda Cortisol FIA Rapid Test Cassette 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 Analyser. 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.

## LIMITATIONS OF THE TEST

1. The Biopanda Cortisol FIA Rapid Test Cassette should be used only with the analyser.
2. The Biopanda Cortisol FIA Rapid Test Cassette 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.
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.

## 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 Cassette 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 Cassette 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 Cassette 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

## REFERENCES

1. Cherceky, C. C., & BJ, B. (2013). Cherceky CC, Berger BJ. Cortisol: plasma or serum. Laboratory tests and diagnostic procedures 6th ed., 388-389.

## 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 $\langle n \rangle$ tests
	Catalogue number		Do not use if package is damaged

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



## Biopanda Reagents Ltd.

Unit 14 Carrowreagh Business Park  
Carrowreagh Road  
Belfast, BT16 1QQ  
United Kingdom  
Tel: +44 (0) 28 95438774  
E-mail: [info@biopanda.co.uk](mailto:info@biopanda.co.uk)  
Website: [www.biopanda.co.uk](http://www.biopanda.co.uk)

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