Estradiol FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

Catalogue Number: FI2-EST-001

A Fluorescence Immunoassay for the quantitative detection of Estradiol (E2) in human whole blood, serum or plasma using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Estradiol FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Estradiol (E2) in whole blood, serum, or plasma.

BACKGROUND

Estradiol (E2), a hormone with a pivotal role in various biological processes, including the regulation of the menstrual cycle, development of secondary sexual characteristics, and maintenance of pregnancy, is primarily synthesized in the ovaries, with additional production in the adrenal glands and placenta during pregnancy. Its effects are mediated through binding to estrogen receptors present in multiple tissues, influencing reproductive function, bone mass, cardiovascular health, and brain function.
Abnormal estradiol levels can serve as diagnostic markers for hormonal disorders such as polycystic ovary syndrome (PCOS), ovarian failure, and hypogonadism. Monitoring estradiol is also essential during infertility treatments to gauge ovarian response and predict ovulation timing. Furthermore, estradiol has been implicated in the development and progression of certain cancers, including breast and endometrial cancer, making it a critical factor in the diagnosis, prognosis, and management of these conditions.

TEST PRINCIPLE

The Estradiol FIA Rapid Test Device is based on fluorescence immunoassay to detect the concentration of Estradiol (E2) in human whole blood, serum or plasma. The sample moves from sample pad to absorbent pad. If the specimen contains Estradiol, it attaches to the fluorescent microspheres-conjugated Estradiol antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Estradiol in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of Estradiol in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device to show Estradiol concentration in specimen.

REAGENTS

The test includes anti-Estradiol antibody coated on fluorescent microspheres and anti-Estradiol 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.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
6. Do not eat, drink or smoke in the area where the specimens and tests are handled.
7. 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.
8. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when specimens are assayed.
9. Do not interchange or mix reagents from different lots.
10. Extremes in humidity and temperatures can adversely affect results.
11. Used testing materials should be discarded in accordance with local regulations.
12. The Biopanda Estradiol FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) 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. Do not freeze.
2. The test must remain in the sealed pouch until use.
3. 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

- 25 x Foil wrapped Estradiol test devices
- 25 x Specimen collection tubes with extraction buffer
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (Estradiol)
- 1 x Package Insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed 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, keep 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 finger-prick 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 can be used as the anticoagulant for collecting the blood specimen.

For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information.

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 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 immediately after opening the foil pouch.
3. Follow the appropriate steps below for the chosen specimen type:
   a. **<u>For venipuncture whole blood/serum/plasma specimens:</u>**
      i. Pipette **20 µl of whole blood/serum/plasma** into the buffer tube.
      ii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.
      iii. Let the diluted specimen homogenise for approximately 1 minute. Diluted specimens should be used as soon as possible.
      iv. **Pipette 75 µl of diluted specimen** into the specimen well (S) of the test device.
   b. **<u>For finger-prick whole blood specimens:</u>**
      i. Wash hands with soap and warm water or clean finger with an

alcohol pad. Allow to dry.

ii. Massage the hand without touching the puncture site by applying pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.

iii. Use a sterile lancet (not provided) to puncture the skin and wipe away the first sign of blood.

iv. Gently apply pressure from palm to the pricked finger so a rounded drop of blood forms over the puncture site.

v. Using the provided capillary dropper and ensuring the dropper is level, touch the open end to the rounded drop of blood without squeezing the dropper bulb. **The dropper will automatically collect the correct volume of blood (approx. 20 µl)**, *see Figure 1 below*.

vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb.

vii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.

viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µl), then add to the specimen well (S) of the test device.

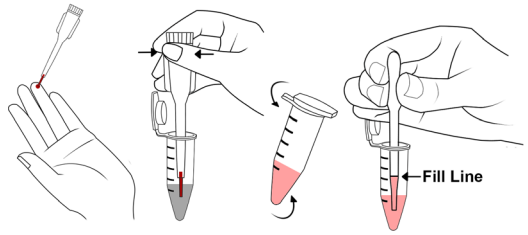

Figure 1

4. Insert the test device into the analyzer test device slot. Then according to user requirements, select either 'Standard test' or 'Quick test' mode.
5. Test results should be read at **15 minutes** using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

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

Linearity range of the test is 10-3000 pg/mL.

QUALITY CONTROL

Each Biopanda Estradiol 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.

EXPECTED RESULTS

Gender	Period	Reference Range (pg/mL)
Male	/	11-44
Female	Follicular Period	31-91
	Ovulation	60-533
	Luteal period	60-233
	Pregnancy	>153
	Menopause	<140

Note: It is recommended that each laboratory establish an actual reference interval based on the population, age, gender, diet, etc. in each region.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
   A comparison study was conducted with 126 clinical specimens with a commercially available test. The correlation coefficient (r) is 0.991.
2. **Analytical sensitivity**
   The test can detect levels of Estradiol as low as 10 pg/mL in whole blood, serum or plasma.
3. **Linearity Range**
   10-3000 pg/mL, R≥0.990
4. **Precision**

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens of Estradiol. 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 of Estradiol. C.V. is ≤15%.

5. **Interfering Substances**
   The following substances do not interfere with the test results at the indicated concentrations:

Substance	Concentration
Haemoglobin	1.5g/dL
Bilirubin	30mg/dL
Albumin	6g/dL
Cholesterol	250mg/dL
Triglyceride	500mg/dL

6. **Cross-Reactivity**
   No cross-reaction was found with the following substances at the indicated concentrations:

Substance	Concentration
Cortisol	600 ng/mL
Estrone	200 ng/mL
Estriol	200 ng/mL
Progesterone	500 ng/mL
Testosterone	20 ng/mL

LIMITATIONS OF THE TEST

1. The Biopanda Estradiol FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Estradiol.
2. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. The test results are based on measuring the levels of estradiol in a specimen. It should not be used as the sole criterion for treatment decisions.

INDEX OF SYMBOLS

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	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 Estradiol FIA Rapid Test Device. 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
Website: www.biopanda.co.uk

Revision date: 02/02/2026