AMH FIA Rapid Test

(Whole Blood/Serum/Plasma)

FI2-AMH-001

A rapid test for detecting Antimullerian hormone 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 AMH FIA Rapid Test Device is intended for *in vitro* quantitative determination of human Antimullerian hormone (AMH) in whole blood, serum or plasma as an aid in the assessment of ovarian reserve function[1], menopause, and polycystic ovary syndrome (PCOS)[2].

SUMMARY

Antimullerian hormone (AMH), also known as mullerian-inhibiting substance, is a dimeric glycoprotein hormone belonging to the transforming growth factor-beta family. It is produced by sertoli cells of the testes in males and by ovarian granulosa cells in females.

Expression during male foetal development prevents the mullerian ducts from developing into the uterus, resulting in development of the male reproductive tract. In the absence of AMH, the mullerian ducts and structures develop into the female reproductive tract. AMH serum concentrations are elevated in males under 2 years old and then progressively decrease until puberty, when there is a sharp decline. In females, serum AMH concentrations are very low at birth, peaking after puberty, decreasing progressively thereafter with age, and becoming undetectable at menopause.

AMH is a product of granulosa cells of the preantral and small antral follicles in women. As such, AMH can also serve as a molecular biomarker for relative size of the ovarian reserve. In humans, this is helpful because the number of cells in the follicular reserve can be used to predict timing of menopause. AMH can also be used as a marker for ovarian dysfunction, such as in women with PCOS.

PRINCIPLE

The Biopanda AMH FIA Rapid Test Device detects AMH based on Fluorescence Immunoassay. The sample moves through the strip from the sample pad to the absorbent pad. If the specimen contains AMH, it attaches to fluorescent microspheres conjugated to anti-AMH antibodies. Any complexes will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of AMH 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 AMH in the sample can be calculated by the Analyser to show the AMH concentration in the specimen.

REAGENTS

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

MATERIALS REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND 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 5 days, 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 one day of collection. Do not freeze whole blood specimens.
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, Sodium citrate, Heparin sodium, and Oxalate potassium 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 dilution 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 should then be tested immediately, or stored at 2–8°C for up to 4 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 rapid test device from the sealed foil pouch and place it on a clean, level surface. The rapid test 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 rapid 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 AMH will be displayed on the screen of the Biopanda Fluorescence Immunoassay Device. The analyser will provide the result in **ng/ml**.

The linearity range of the AMH FIA Rapid Test is 0.05–25 ng/ml.

QUALITY CONTROL

Each AMH 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 OF THE TEST

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

EXPECTED RESULTS

Gender	Age (years)	Concentration (ng/ml)
Male	>12	0.9~13
Female	12–19	0.49~7.8
	20–29	0.89~12
	30–39	0.15~8.1
	40–50	<5.5
	>51	<0.88

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, race, etc. in their region.
Menopausal women or women with premature ovarian failure of any cause, including after chemotherapy, have very low AMH levels.

PERFORMANCE CHARACTERISTICS

1. **ANALYTICAL SENSITIVITY**: The Biopanda AMH FIA Test Device can detect levels of AMH as low as 0.05 ng/ml in whole blood, serum or plasma.
2. **LINEARITY RANGE**: 0.05–25 ng/ml, R≥0.990
3. **PRECISION**
   INTRA-LOT PRECISION
   Within-run precision has been determined by using 10 replicates of 2 specimens containing 1.0 ng/ml and 15.0 ng/ml of AMH. 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%.
4. **METHOD COMPARISON**
   The assay was evaluated on 87 clinical specimens and compared against a commercially available AMH test kit. The correlation coefficient(r) is 0.972

REFERENCES

1. Broer SL, Eijkemans MJ, Scheffer GJ, van Rooij IA, de Vet A, Themmen AP, Laven JS, de Jong FH, Te Velde ER, Fauser BC, Broekmans FJ (August 2011). "Anti-mullerian hormone predicts menopause: a long-term follow-up study in normoovulatory women". The Journal of Clinical Endocrinology and Metabolism. 96 (8): 2532–9. doi:10.1210/jc.2010-2776. PMID 21613357.
2. Visser JA, de Jong FH, Laven JS, Themmen AP (January 2006). "Anti-Müllerian hormone: a new marker for ovarian dysfunction". Reproduction. 131 (1): 1–9. doi:10.1530/rep.1.00529. PMID 16388003

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	Σ	Contains sufficient for <*n*> tests
REF	Catalogue number		Do not use if package is damaged

Thank you for purchasing Biopanda's AMH 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

Effective date: 03/04/2025