CE

# AMH Rapid Test Kit

Instructions for use | IVD For in vitro diagnostic use only.

REF A02041002 | Σ 25 Tests

## 【Product Name】

AMH Rapid Test Kit

## 【Intended Use】

The Anbio AMH Rapid Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for quantitative measurement of anti-Mullerian hormone (AMH) in human whole blood, serum or plasma. The test kit is used as an aid in the functional diagnosis of ovarian.

⚠ ***For professional use only.***

## 【Summary】

Anti-Mullerian hormone (AMH) is a member of the transforming growth factor beta superfamily, which was first discovered by Professor Alfred Jost in 1974. AMH is a disaccharide protein composed of two identical 70kD subunits linked by disulfide bonds, with a relative molecular weight of 140kd; the human AMH gene is located in the short arm of chromosome 19, with a size of 2.4-2.8kb, and contains five exons.Anti Mullerian hormone (AMH) plays an important role in the development of gonadal organs and is one of the important markers of gonadal function in men and women. In male, AMH is mainly produced by Leydig cells of testis, which starts from embryo formation and runs through life; in the development of male fetus, AMH leads to the degeneration of Muller's duct and forms a normal male reproductive canal. In women, AMH is mainly produced by ovarian granulosa cells. Serum AMH level remains at a lower level than that in men. From puberty, serum AMH level gradually decreases with time.

## 【Test Principle】

The Anbio AMH Rapid Test Kit is based on fluorescence immunoassay technology. The Anbio AMH Rapid Test Kit uses a sandwich immuno detection method. When sample is added to the sample well of the test, the fluorescence-labeled detector AMH antibody binds to AMH antigen in the specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and AMH are captured to anti-AMH antibody that has been immobilized on test strip. Thus the more AMH antigen is in the specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of AMH captured and Anbio FIA Meter shows AMH concentration in the specimen.

## 【Main Components】

The following components are included in the AMH Rapid Test Kit:

**Supplied materials:**

| Component | Main Ingredients |
|---|---|
| Test Cartridge | 1) T line: Mouse anti-AMH monoclonal antibody (coated)<br>2) C line: Goat anti-rabbit IgG polyclonal antibody<br>3) Binding pad: Fluorescent microsphere-labeled mouse anti-AMH monoclonal antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody |
| IC Card | / |
| Whole Blood Buffer | 10mmol/L PBS |
| Tube | / |

**Optional Materials:**

1. Sterile lancets (for Fingerstick Whole Blood only)
2. Alcohol pads (for Fingerstick Whole Blood only)
3. Disposable pipettes (50μL)
4. AMH Quality control (LEVEL 1, LEVEL 2)

**Materials Required but not Provided:**

1. Transfer Pipette Set
2. Specimen Collection Containers
3. Timer
4. Centrifuge (for Plasma/Serum only)
5. Anbio FIA Meter (model number: AF-100, AF-100s, AF-1200, AF-100C)

## 【Storage Conditions and Shelf Life】



| Component | Storage- Temperature limitation | Stability |
|---|---|---|
| Test Cartridge |  | The shelf life is up to 24 months. Please refer to use-by date on the label.<br>Test Cartridge should be used within 1 hour after opening the pack. |
| IC Card | | / |
| Whole Blood Buffer | | The buffer is stable up to 24 months. Please refer to use-by date on the label. |

## ⚠ 【Warnings and Precautions】

1.This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio AMH Rapid Test Kit is only operational in the Anbio FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector buffer tubes for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector buffer tubes should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

## 【Specimen Collection and Preparation】

The test can be performed with serum or plasma or whole blood.The plasma and whole blood samples are recommended to use heparin for anticoagulation. Other body fluids and samples may not get accurate results.

**For Serum and Plasma:**

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

**For Whole Blood Collected by Venipuncture:**

1.Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant.
2.It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3.It's not suitable to test the whole blood samples storing at 2℃～8℃ for more than 2 days.

**For Fingertip Whole Blood Samples:**

1.Clean the puncture site with the alcohol pad.
2.After the alcohol is dried, the fingertips are punctured with safety Lancet to form blood droplets.
3.Lay the disposable pipettes, do not squeeze, automatically collect fingertip whole blood for 50μL.
4. It is recommended that specimens should be tested immediately.

## 【Test Procedure】

Refer to Anbio FIA Meter Operation Manual (attached to Anbio FIA Meter) for the complete instructions on use of the Test. The test should be operated in room temperature.

**Step1:Preparation**

Check/ Swipe the IC Card information to the equipment.

**Whole blood:**Take 50 μL of whole blood buffer into the empty centrifuge tube by transfer pipette.

**Caution:**When the sample is serum/plasma, proceed to step 4.

**Step2:Sampling**

**Whole blood:** Take 50μL of whole blood sample with a transfer pipette, and add it to the centrifuge tube.

**Step3: Mixing**

**Whole blood:** Close the lid of centrifuge tube and mix the specimen by shaking or tapping 6-8 times, until the specimen completely mixed. Let it stand 1 minute.

**Step4: Loading**

**Serum / plasma:**Take 50μL of serum or plasma samples with a transfer pipette, load it into the sample well of the Test Cartridge.

**Whole blood:**Take 50μL of sample mixture with a transfer pipette and load it into the sample well of the Test Cartridge.

**Step5:Testing**

**Standard test:** Insert the Test Cartridge onto the Test Cartridge Holder and click "Timing Test". 15 minutes later,

the result will show in the display and print out when click “Print”.
**Quick test:** Put the Test Cartridge on the operation platform.15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click “Quick Test”. The result will show in the display and print out when click “Print”.

## 【Limitations of Procedure】

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The results of Anbio AMH Rapid Test Kit should be evaluated with all clinical and laboratory data available. If AMH test results do not agree with the clinical evaluation, additional tests should be performed.
3. Incorrect results can be caused by interference from some similar substance in the sample.
4. Other factors may interfere with Anbio AMH Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

## 【Quality Control】

- Internal procedural controls are included in the test. When testing, the quality control line (C line) will show a certain luminescence intensity, which is an internal procedural control. It confirms that a sufficient volume of samples has been added and that the correct procedure has been performed.
- Anbio AMH Control is recommended for Anbio AMH Rapid Test Kit and can be used in the following cases: When a box of a new lot is opened; When the Anbio FIA Meter or Anbio AMH Rapid Test Kit are not working properly; When the result and the symptoms are not consistent or if there are doubts about their accuracy.

Note: Please refer to the Instructions For Use of Anbio AMH Control for detailed operation.

## 【Interpretation of Results】

The Anbio FIA Meter calculate the test result automatically and displays AMH concentration of the test sample in terms of ng/mL.
Using healthy population samples that meet the requirements for AMH testing, the analysis of the test results concludes that the reference range for AMH Rapid Test Kit is as follows:

| Gender | Number | Age | Reference value(ng/mL) |
|---|---|---|---|
| Male | 120 | / | 0.82-13.65 |
| Female | 120 | 20-24 | 1.35-10.92 |
| | 120 | 25-29 | 0.93-8.89 |
| | 120 | 30-34 | 0.55-8.41 |
| | 120 | 35-39 | 0.19-7.04 |
| | 120 | 40-44 | <0.1-5.09 |
| | 120 | 45-50 | <0.1-3.13 |

Note: Individual reference range is suggested to be established for each laboratory.

## 【Performance Characteristics】

**Limits and Range**
Limit of Detection: 0.1 ng/mL;
Limit of Quantitation: 0.2 ng/mL;
Measuring range: 0.2-20 ng/mL.
**Precision**
Precision was determined with Anbio test kits, samples, and controls according to the CLSI (clinical and Laboratory Standards Institute) protocol (EP05- A3):
(1) 3 batches of test kits, repeated 10 times per batch (n=30).

| ng/mL | Intra-batch | | | | | | Inter-batch | |
|---|---|---|---|---|---|---|---|---|
| | Batch 1 | | Batch 2 | | Batch 3 | | | |
| | SD | CV% | SD | CV% | SD | CV% | SD | CV% |
| 0.51 | 0.044 | 8.63% | 0.051 | 9.81% | 0.048 | 9.60% | 0.047 | 9.22% |
| 2.00 | 0.188 | 9.17% | 0.208 | 10.30% | 0.151 | 7.82% | 0.185 | 9.25% |
| 9.96 | 0.831 | 8.55% | 1.006 | 10.02% | 0.869 | 8.57% | 0.893 | 8.97% |

(2) 3 laboratories with duplicate testing 5 times a day for 5 days (n = 75).

| ng/mL | Repeatability | | Intra laboratory precision | | Inter laboratory precision | |
|---|---|---|---|---|---|---|
| | SD | CV% | SD | CV% | SD | CV% |
| 0.50 | 0.037 | 7.40% | 0.039 | 7.80% | 0.039 | 7.80% |
| 2.01 | 0.172 | 8.56% | 0.172 | 8.56% | 0.178 | 8.86% |
| 10.08 | 0.858 | 8.51% | 0.88 | 8.73% | 0.88 | 8.73% |

**Limitations-Interference**
Detection of the effects of the following endogenous substances on assay performance. Interfering substances detected in the listed concentration range had no effect on the results.

| Compound | Concentration |
|---|---|
| Bilirubin | 350μmol/L |
| Triglycerides | 40mmol/L |
| Hemoglobin | 2g/L |
| RF | 1500IU/mL |
| HAMA | 1000ng/mL |
| Antinuclear antibody | 1:640 |

**Limitations-Cross-Reactivity**
The following substances do not interfere with the AMH test results at the indicated concentrations.

| Cross material | Concentration |
|---|---|
| Inhibin A | 100 ng/mL |
| Activin A | 100 ng/mL |
| FSH | 500 mIU/mL |
| LH | 500 mIU/mL |
| E2 | 10 ng/mL |
| PROG | 50 μg/mL |
| TEST | 500 ng/mL |

## 【Bibliography of Suggested Reading】

1.The possible role of AMH in shortening the gubernacular cord in testicular descent: A reappraisal of the evidence[J] . John M. Hutson,Francisco A. Lopez-Marambio. Journal of Pediatric Surgery . 2017 (10);
2.Serum concentration of anti‐Müllerian hormone is not associated with semen quality[J] . L. Aksglaede,I. A. Olesen,E. Carlsen,J. H. Petersen,A. Juul,N. J?rgensen. Andrology . 2018 (2);

## 【Index of Symbols】

| | | | |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Do not re-use |
| EC REP | Authorized representative in the European Community/ European Union | | Consult instructions for use or consult electronic instructions for use |
| | Caution | | Manufacturer |
| | Temperature limit | LOT | Batch code |
| | Use-by date | | Keep dry |
| | Keep away from sunlight | REF | Catalog number |
| | Date of manufacture | Σ | Contains sufficient for <n> tests |
| CE | The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC | | Do not use if package is damaged and consult instructions for use |

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