# AMH Rapid Quantitative Test

Catalog No.BT2213

## INTENDED USE

The Biotime AMH Rapid Quantitative Test is intended to quantify the concentration of AMH(Anti-Müllerian hormone) in human serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of ovary function and fertility assessment.
-Fluorescence immunoassay
-Ovary function and fertility
For in vitro diagnostic use only. For professional use only.

## INTRODUCTION

Anti-Müllerian hormone (AMH), also known as Müllerian-inhibiting hormone (MIH), is a glycoprotein hormone structurally related to inhibin and activin from the transforming growth factor beta superfamily, whose key roles are in growth differentiation and folliculogenesis. In male mammals, AMH prevents the development of the Müllerian ducts into the uterus and other Müllerian structures. In females AMH is expressed by granulosa cells of the ovary during the reproductive years, and limits the formation of primary follicles by inhibiting excessive follicular recruitment by FSH. In healthy females AMH is either just detectable or undetectable in cord blood at birth and demonstrates a marked rise by three months of age; while still detectable it falls until four years of age before rising linearly until eight years of age remaining fairly constant from mid-childhood to early adulthood. From 25 years of age AMH declines to undetectable levels at menopause. Comparison of an individual's AMH level with respect to average levels is useful in fertility assessment, as it provides a guide to ovarian reserve and identifies women that may need to consider either egg freezing or trying for a pregnancy sooner rather than later if their long-term future fertility is poor. AMH has also been considered to be a tool or biomarker that can be used to diagnose or indicate polycystic ovary syndrome [1-2].

## PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer is mixed and applied into the test cartridge, the AMH in the sample and the mouse anti-AMH monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with AMH specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final sandwich-like reaction complex. Thus the fluorescent signal on detection line is positively correlated with the concentration of AMH in human serum .
The fluorescent signal from microspheres of T line will be detected and calculated according to the calibration curve (in SD card provided with the reagent) to represent the concentration of AMH in human serum .

## PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridge that is contaminated with blood or other liquids on the surface. It may cause damages to the instrument.

## MATERIAL

**Material Provided**
1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1copy/kit
**Material Required But Not Provided**
1. Biotime FIA Analyzer
2. Transfer Pipette Set (range 10~100μL size)
3. Specimen collection containers
4. Timer

## STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

## SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with serum specimen .
2. The specimen collection container should be immune tube or pro-coagulant tube for serum .

3. Sample collection: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected timely, it can be stored in refrigerator at 2-8℃ for no more than 7 days，or at -20℃ for no more than 6months. Samples must be recovered to the room temperature before tests.
4. Separate the serum from blood as soon as possible to avoid hemolysis.

## TEST PROCEDURE

Refer to Biotime FIA Analyzer Operation Manual for the complete instructions on use of the Test. The test should be operated at room temperature（~25℃）.
**Step 1: Preparation**
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
**Step 2: Sampling**
Take 50μL of serum with a transfer pipette and add it to the buffer tube.
**Step 3: Mixing**
Mix well the specimen with buffer by tapping or inverting the tube.
**Step 4: Loading**
Take 80μL of sample mixture and load it into the well of the test cartridge.
**Step 5: Testing**
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 10 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

## REFERENCE INTERVAL.

| / | / | 5th percentile（ng/mL） | 10th percentile（ng/mL） | median（ng/mL） | 90th percentile（ng/mL） | 95th percentile（ng/mL） |
|---|---|---|---|---|---|---|
| **Male** | / | 1.43（0.256-1.97） | 2.15（1.35-2.43） | 4.79（4.35-5.35） | 10.1（9.14-11.6） | 11.6（10.3-17.0） |
| **Female** | 20-24 (years) | 1.66（0.862-1.85） | 1.88（1.49-2.28） | 3.97（3.55-4.33） | 7.29（6.82-10.1） | 9.49（7.38-11.5） |
| | 25-29 (years) | 1.18（0.853-1.81） | 1.83（1.18-2.07） | 3.34（3.03-3.87） | 7.53（6.74-9.16） | 9.16（7.63-10.1） |
| | 30-34 (years) | 0.672（0.473-0.932） | 0.946（0.602-1.19） | 2.76（2.34-3.55） | 6.70（5.57-7.64） | 7.55（6.76-9.34） |
| | 35-39 (years) | / | 0.777（0.159-0.932） | 2.05（1.78-3.24） | 5.24（4.83-7.34） | / |
| | 40-44 (years) | / | 0.097（0.021-0.247） | 1.06（0.743-2.13） | 2.96（2.59-5.70） | / |
| | 45-50 (years) | / | 0.046（0.018-4.16） | 0.223（0.125-0.498） | 2.06（0.018-4.16） | / |
| | PCOS Female | 2.41（1.67-3.01） | 3.12（2.29-3.77） | 6.81（6.30-7.42） | 12.6（11.5-17.1） | 17.1（13.3-20.3） |

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

## LIMITATIONS OF PROCEDURE

1. The test sample should be serum specimen.
2. 2. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies [3-4].
3. Other factors also can induce the false results, include the technology, operational error and other sample factors.

## PERFORMANCE CHARACTERISTICS

**Accuracy**
Test cartridges from same lot were tested with AMH control of three different levels of concentration, mean and Bias% are calculated, Bias% are within ±15.0%.
**Assay Range:** 0.1~25.0ng/mL
**The Lowest Detection Limit:** 0.1ng/mL
**Linearity**
A serial concentration of AMH controls at 0.1~25.0ng/mL were tested, the Correlation Coefficient (R) is≥0.9900.
**Precision**
**Intra-Lot Precision**
Within-run precision has been determined by using 10 replicates from same lot to test with AMH control. The C.V. is ≤10.0%.
**Inter-Lot Precision**
Between-run precision has been determined by using 30 replicates from random 3 continuous lots to test with AMH control. The C.V. is ≤15.0%.

## SYMBOLS

| Symbol | Description | Symbol | Description |
|--------|-------------|--------|-------------|
| **REF** | Catalogue number | **IVD** | In vitro diagnostic medical device |
| **LOT** | Batch code | | Consult instructions for use |
| | Date of manufacture | | Keep dry |
| | Use-by date | | Keep away from sunlight |
| | Manufacturer | 8℃ / 2℃ | Temperature limit |
| | Do not re-use | 30℃ / 2℃ | Temperature limit |
| **EC** \| **REP** | Authorized representative in the European | **CE** | CE mark |
| Σ | Contains sufficient for \<n\> tests | | |

## BIBLIOGRAPHY OF SUGGESTED READING

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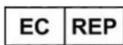
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