AMH Test Kit User Manual

(Dry Fluorescence Immunoassay)

[NAME]

AMH Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
20 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

AMH Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of AMH (anti-mullerian hormone) in serum. AMH is a member of the transforming growth factor beta superfamily, which is a disaccharide protein composed of two identical 70KD subunits linked by disulfide bonds. AMH can be used as an indicator for the diagnosis of ovarian reserve function and polycystic ovary syndrome (PCOS).

[PRINCIPLE]

AMH Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will diffuse forward due to capillary action, then the AMH of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody, and the other fluorescence microspheres are attached to the control area. When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. AMH test strip in a sealed pouch with desiccant..... 25 tests
2. QR code card for calibration..... 1 piece
3. User Manual..... 1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-3000 Automatic Fluorescence Immunoassay Analyzer
9. LS-3100 Automatic Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human serum. Other bodily fluids and samples may not get the accurate result.
2. At room temperature(15°C-30°C), the test should be performed within 6 hours after the sample collection.
3. Blood sample can be stored at 2°C-8°C for 5 days .Serum and plasma sample can be stored at -20°C for 6 months. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
4. The sample before testing should be recovered to room temperature (15°C-30°C).Microbial contamination samples can not be used.
5. Frozen samples should be completely melted, rewarmed and mixed completely before use. Avoid repeated freeze-thaw. It is suggested freeze-thaw of sample should not more than 1 time .If there is sediment in thawed samples, please centrifuge the samples before testing.
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

Step 1: Preparation

Before the test, the sample and test strip should be recovered to room temperature (15°C -30°C).

Step 2: Calibration

Open the device and perform QR code calibration when necessary.
Note: It is required to perform QR code calibration when starting to use one new batch of kit.

Step 3: Adding the Sample

Draw 100μL of sample and load it into the sample well of test strip. Set the timer and count down. Incubate the test strip with the sample mixture at room temperature for 10 minutes.

Step 4 Testing

Insert the test strip into the analyzer to start test. For detailed information on how to operate the device, please refer to the User Manual of the device.

Result are displayed on main screen or printed automatically.

Discard the used test strip after released from the analyzer considering it to be potentially infectious.

[EXPECTED VALUE]

The following reference interval was obtained after statistical analysis of the confidence interval for the tests of the content of AMH in serum samples of healthy people:

Male：1.46-11.6ng/mL（95%）;
Female 20-24 years old：1.66-9.49ng/mL (95%);
Female 25-29 years old：1.18-9.16ng/mL (95%);
Female 30-34 years old：0.672-7.55ng/mL (95%);
Female 35-39 years old：0.777-5.24ng/mL (95%);
Female 40-44 years old：0.097-2.96ng/mL (95%);

Female 45-50 years old：0.046-2.06ng/mL (95%).

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 50ng/mL, the analyzer displays “>50ng/mL”, and if the result is less than 0.1ng/mL, the analyzer displays “<0.1ng/mL”. Specific data can be exported through related software as needed.

[LIMITATION OF THE PROCEDURE]

1. The test result of this kit are only one of the diagnostic aids for the clinicians.
2. Samples containing interfering substances may affect the test results, and the maximum allowable concentrations are: hemoglobin 5mg/mL, bilirubin 3mg/mL, and triglyceride 10mg/mL.

[PRODUCT PERFORMANCE]

1. Measuring Range: 0.1-50ng/mL.
2. Lower Detection Limit: ≤0.1ng/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%. In the range of 0.1-50ng/mL, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. This kit is for in vitro diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix components from different kit Lots.

[REFERENCES]

1. Xiong Ziwei, Hu Jian, Chen Xinyu, et al. The value of anti-Mullerian hormone in the diagnosis of polycystic ovary syndrome. Molecular Imaging Journal, 2015, 38(2): 80-83.
2. Wu Xueqing, Kong Rui, Tian Li, et al. Expert consensus on ovarian hyporesponsiveness. Reproductive and Contraception, 2015, 2: 71-79.
3. Tan Jiaqi, Chen Xiaoli, Li Yu, et al. Study on the value of anti-Mullerian hormone in predicting ovarian response. Journal of Practical Obstetrics and Gynecology, 2015, 31(8): 583-586.

Lansion Biotechnology Co., Ltd.

Add: No.2, Qiande Road, Jiangning District, B Nanjing, China

Website: en.lansionbio.com Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

EC REP

Venezuela

Email: inmunofluorescencia@lansionbio.com.ve

Website: https://lansionbio.com.ve/

Revision Date: July 23 , 2020

Version Number: 0.0

Production date and expiration see the label.