Chuangxingwell

CE

Anti-Müllerian Hormone

AMH Rapid Test Kit
Package Insert

For in vitro diagnostic use only.
For professional use only.

IVD

INTENDED USE

AMH Rapid Test Kit is intended for in vitro quantitative determination of AMH in human serum and plasma samples. This test can be used as an aid in indicating ovarian functional reserve, and also help to diagnose menstrual disorders or to monitor the health of women.

SUMMARY

Anti-Müllerian hormone (AMH), also called Müllerian inhibiting substance (MIS), is a homodimeric glycoprotein from the TGF- family. It plays a major role in cell growth and differentiation. AMH molecular weight is 140 kDa.

AMH plays a role in gender differentiation during embryo development. Under the influence of AMH secreted by Sertoli cells of the embryonic testis, the Müllerian ducts regress in male fetuses, which leads to the normal development of male genitals. The absence of AMH allows the Müllerian ducts to further develop, resulting in the internal female genital organs.

AMH is a marker for ovarian functional reserve because it is formed only by the primary follicles, which are capable of maturation, and the secondary follicles. In women over 30 and particularly those over 35 years of age, AMH can be used as a screening test to assess fertility status. Elevated AMH concentrations are measured in the serum of patients with PCOS (polycystic ovary syndrome), and the concentration is also greatly increased in an ovulatory cycles. Besides, the AMH level falls continuously with increasing age, corresponding to the loss of ovarian functional reserve.

In males, the determination of AMH may be useful in the investigation of gonadal function, the differential diagnosis of intersexuality and cryptorchidism/anorchism and the diagnosis of precocious/late puberty. AMH can be used to detect the presence of testes in cryptorchidic boys.

PRINCIPLE

The test uses an anti-human AMH monoclonal antibody I conjugated with fluorescence latex coated on the nitrocellulose membrane and another anti-human AMH monoclonal antibody II coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labeled anti-human AMH antibody I binds with the AMH in sample and forms marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then the marked antigen-antibody complex is captured on the test line by anti-human AMH antibody II . The fluorescence intensity of the test line increases in proportion to the amount of AMH in the sample.

Then Insert test card into the Immunofluorescence Quantitative Analyzer, the concentration of AMH in sample will be measured and displayed on the screen. The value will be stored in Analyzer and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

A kit contains:

Package specifications: 25 tests/box, 10 tests/box

1) Test Cassettes in the sealed pouches with desiccants
2) Disposable pipet
3) Sample diluent
4) Package Insert: 1 piece/box
5) SD card: 1 piece/box

Sample diluent composition: Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

A test card consists of: A plastic shell and a reagent strip which is composed of a sample pad (one end of the membrane is coated with fluorescence latex-labelled anti-human AMH monoclonal antibody I) nitrocellulose membrane (test line is coated with another AMH monoclonal antibody II and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or Interchange different batches of kits.

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened.

Store the sample diluent at 0-30°C with a valid period of 24 months.

Store the sample diluent at 2-8°C for better results.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test kit can be used for serum and plasma samples. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2-8°C or stored at -20°C for 3 months before testing.
4. Refrigerated or frozen sample should be reached room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples .
6. SAMPLE VOLUME : 200 ul.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No .. Perform "SD card" calibration when necessary.
4. Enter testing interface of Immunofluorescence Quantitative Analyzer.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***200µl*** of sample into one tube of sample diluent and mix thoroughly. Then drop ***100µl*** of sample mixture into sample port on the test card.
8. Reaction time: 15 minutes. Insert the test card into Immunofluorescence Quantitative Analyzer and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

NOTES:

1. It is required to perform "SD card" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits.
3. Make sure the test cassette and the sample insertion are correct and complete.

TEST RESULTS

Immunofluorescence Quantitative Analyzer can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.

Measuring range of the AMH test kit is 0.10 ng/mL-20.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative sample, and the recommended dilution ratio is less than 3 times.

EXPECTED VALUE

The expected normal value for AMH and was determined by testing samples from apparently healthy males, women who don't use birth control pills and women with PCOS.

Reference range of AMH:

Group		N	95% Reference Interval ng/mL
Male		200	1.43~11.60
Female (Age)	20~24	121	1.66~9.49
	25~29	148	1.18~9.16
	30~34	120	0.67~7.55
	35~39	53	0.78~5.24
	40~44	48	0.10~2.96
	45~50	28	0.10~2.06
	PCOS	150	2.41~17.10

It is recommended that each laboratory establish its expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10-20.00 ng/mL
Lower Detection Limit	≤0.10 ng/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Triglyceride	Bilirubin
Concentration (Max)	25 g/L	0.1g/L

REFERENCES

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3. Al-Qahtani A, Muttukrishna S, Appasamy M, et al. Development of a sensitive enzyme immunoassay for anti-Müllerian hormone and the evaluation of potential clinical applications in males and females [J]. Clin Endocrinol (Oxf), 2005, 63 (3): 267-273.
4. Andersen JM, Heming H, Witczak 0, et al. Anti -Müllerian hormone in seminal plasma and serum: association with sperm count and sperm motility [J]. Hum Reprod, 2016, 31 (8): 1662-1667.
5. Murase H, Saito S, Amaya T, et al. Anti-Müllerian hormone as an indicator of hemi-castrated unilateral cryptorchid horses [J]. J Equine Sci , 2015, 26 (1): 15-20.

INDEX OF SYMBOLS

	Caution	IVD	In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
CE	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
LOT	Batch Code		Do Not Use if Package is Damaged
REF	Catalogue Number	Σ	Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
EC REP	Authorized representative in the European Community		

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Jinan Chuangxingwell Biotech Co., Ltd.
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