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CE IVD

AMH

Fast Test Kit

(Immunofluorescence Assay)

IF1066 for Getein1100
IF5066 for Getein1160
IF3066 for Getein1180
REF IF4066 for Getein1200
IF2066 for Getein1600

User Manual

INTENDED USE

AMH Fast Test Kit (Immunofluorescence Assay) 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-β 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 anovulatory cycles. Besides, the AMH level falls continuously with inreasing 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 Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/ Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180 , Getein1200 and Getein1600), the concentration of AMH in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:

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

1) Getein AMH test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein AMH test cards
User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent composition:

Phosphate buffered saline, preservative.

4. 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.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.

Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

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 nt 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 can be used for s***erum 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 ***(for Getein1100/Getein1160/ Getein1180): 100 μL.***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein1100.

3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent and mix thoroughly. Then drop ***100 μL*** of sample mixture into sample well on the test card.
6. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

1. Confirm SD card lot No. in accordance with test kit lot No..Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table,horizontally placed.
5. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent and mix thoroughly. Then drop ***100 μL*** of sample mixture into sample well on the test card.
6. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position of Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kit for Getein1100/Getein1160/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

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. Interferents in samples 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

1. Broer SL, Broekmans FJ, Laven JS, et al. Anti-Müllerian hormone: ovarian reserve testing and its potential clinical implications [J]. Hum Reprod Update, 2014, 20 (5): 688-701.
2. de Kat AC, Broekmans FJ, Laven JS, et al. Anti-Müllerian Hormone as a marker of ovarian reserve in relation to cardio metabolic health: a narrative review [J]. Maturitas, 2015, 80 (3): 251-257.
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, Herning H, Witczak O, et al. Anti-Müllerian hormone in seminal plasma and serum: association with sperm count and sperm motility [J]. Hum Reprod, 2016, 31 (8): 16621667.
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.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on AMH Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing the AMH Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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