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CE IVD

AMH

Fast Test Kit

(Immunofluorescence Assay)

IF1066 for Getein 1100
IF5066 for Getein 1160
IF3066 for Getein 1180
REF IF4066 for Getein 1200
IF2066 for Getein 1600

Instructions for Use

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. For professional and laboratory use only.

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. The molecular weight of AMH 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 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

AMH Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence labelled AMH monoclonal antibody binds with the AMH in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another AMH monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of AMH in sample. Fluorescent signals intensity can be analyzed by applicable device thus the AMH in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
AMH test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*AMH test card

A test card consists of: Fluorescence labelled AMH monoclonal antibody, AMH monoclonal antibody and polyclonal IgG antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 contained in each tube consists of:

- Sample diluent main contains phosphate buffer (20 mmol/L), NaN_3 (<0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box main consists of:

- Phosphate buffer (20 mmol/L), NaN_3 (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

- For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
- For test card of Getein 1200/Getein 1600: 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 test card if the foil pouch is damaged.
3. Do nt open pouches until ready to perform the test.
4. Do not reuse the test card and the disposable pipet.
5. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.

SPECIMEN COLLECTION AND PREPARATION

1. This test 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 (for Getein 1100/Getein 1160/Getein 1180): 100 μL

TEST PROCEDURE

1. Before use, you must carefully read the instructions for use and operate in strict accordance with the instructions, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

(1) Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
(2) Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details)
(3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
(4) Deliver ***100 μL*** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port "S" on the test card.
(5) ***Reaction time: 15 minutes***. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

(1) Confirm SD card lot No.in accordance with test kit lot No. Perform calibration using the SD card when necessary.
(2) Enter testing interface of Getein 1160/Getein 1180.
(3) Select the corresponding sample model on the analyzer

(refer to the user manual of analyzer for details)

(4) Remove the test card from the sealed pouch before use. Horizontally place the test card.

(5) Deliver ***100 μL*** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port "S" on the test card.

(6) Insert the test card into Getein 1160/Getein 1180 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 Getein 1200/Getein 1600:

(1) Insert the test card cartridge into the analyzer, each test card cartridge for Getein 1200/Getein 1600 contains a specific SD card which can calibrate automatically.

(2) Place the sample diluent at the correct position.

(3) Select the corresponding sample model on the analyzer (refer to the user manual of analyzer for details)

(4) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

Make sure insertion of the test card cartridge and the sample are correct and complete.

TEST RESULTS

AMH Fast Test Kit (Immunofluorescence Assay) results are provided in ng/mL. Results in ng/mL may be converted to pmol/L as shown with an example below.

Example for the conversion of units

AMH Fast Test Kit (Immunofluorescence Assay) result as	
reported by the system (example)	1.00 ng/mL
The reported example result equals:	7.14 pmol/L

Samples initially outside the measuring range may be diluted with sample diluent, measuring range can be up to 60 ng/mL through 3-fold dilution.

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 determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10~20.00 ng/mL
Limit of Detection	≤ 0.10 ng/mL
Within-Run Precision	≤ 10%
Between-Lot 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	Concentration (Max)
Triglyceride	25 g/L
Bilirubin	0.1 g/L

REFERENCES

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3. Yen, S S C, The Human Menstrual Cycle: Neuroendocrine regulation. In Reproductive Endocrinology. Edited by Yen, S S C and Jaffe, R B Philadelphia, PA:W B Saunders Co.1911,273-308.
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5. Hall JE. Polycystic ovarian disease as a neuroendocrine disorder of the female reproductive axis. Endocrinol Metab Clin North Am. 1993;22(1):75-92.6. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
7. EN ISO 18113-2:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

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		Caution

Thank you for using AMH Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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