Anti-Mullerian Hormone (AMH) Rapid Quantitative Test (Fluorescence immunoassay)
User manual

【Product Name】

Anti-Mullerian Hormone (AMH) Rapid Quantitative Test (Fluorescence immunoassay)

【Packing Specification】

25 Tests/kit

【Intended Use】

The kit is used for quantitative determination of AMH in human whole blood， serum or plasma. It is mainly used to evaluate ovarian reserve and assist in the diagnosis of polycystic ovary syndrome .

【Test principle】

The Diagnostic Kit for AMH is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of AMH. The AMH antigen in the sample was first bound with the conjugated compound of fluorescent labeled AMH monoclonal antibody, then moved and combined with another AMH monoclonal antibody fixed on the nitrocellulose membrane, and the double antibody sandwich complex was formed at the detection line of the cellulose nitrate membrane. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25	The product consists of fluorescent pat (coated with fluorescently-labeled AMH antibody), nitrocellulose membrane (coated with AMH antibody and Goat anti mouse IgG antibody), absorbent paper and PVC soleplate.
Sample diluent	25 (0.3mL/ tube)	Phosphate buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage Conditions and Validity】

The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20%～90% relative humidity.

The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable Instrument】

NIR-1000 dry fluoroimmunoassay analyser produced by WWHS Biotech. Inc.

【Sample Requirements】

1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing heparin, citrate or EDTA as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃~8℃ for 24 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test procedure】

1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser according to the instruction manual of the instrument, and carry out quality control verification according to the instruction manual of the instrument（Note: the reagent has been calibrated in advance, and the calibration curve parameters of each batch of reagent have been stored in the information card. The information card is inserted before use, so it is not necessary to calibrate again, and the test can be carried out only after the quality control is passed. Otherwise, the cause should be found out before testing.)
3. Remove the test card from the aluminum foil bag and use it within 15 minutes.
4. Place the test card on a clean horizontal table and mark it horizontally.
5. Mix 100μL of sample with 300μL of sample diluent. Apply 100 μL of diluted samples to the well of the test card.
6. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser, read and record the results at 10 minutes after addition of samples, then dispose of used test appropriately.

【Reference Interval】

Test and analyze the AMH from healthy people serum, and use the 95 percentile method to determine the AMH reference interval.

Sex	Age	Reference Interval (ng/mL)
Adult male	～	0.92～13.89
Female	20～29	0.88～10.35
	30～39	0.31～7.86

	40～50	≤5.07

It is strongly recommended that each laboratory should determine its own normal and abnormal values.

【Interpretation of test results】

1. The kit can be used for auxiliary test only. If test result is abnormal, retest timely and judge combined with clinical symptoms.
2. For samples whose AMH concentration is lower than 0.10ng/mL and higher than 16.00ng/mL, test result is “0.10ng/mL” and “16.00ng/mL” respectively.

【Limitation of test method】

1. This kit is only used to detect human serum/plasma/whole blood samples
2. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
3. The triglyceride content in the sample does not exceed 15mg/mL, the hemoglobin content does not exceed 10mg/mL, the bilirubin content does not exceed 0.5mg/mL, the cholesterol does not exceed 10mg/mL, and the relative deviation of the measurement results does not exceed ±15.0%.
4. When AMH concentration of samples reaches 160.00ng/mL, there is no hook effect.
5. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
6. When RF concentration of samples is less than 2000IU/mL, relative deviation of test result is limited to ±10.0%.
7. For samples exceeding the linearity range, test cannot be conducted after dilution.
8. Inhibin A (≤100ng/mL), Activin A (≤100ng/mL), LH (≤500mIU/mL), FSH (≤500mIU/mL) several commonly used drugs in the sample (Cefoxitin ≤2500mg/ L. Metformin≤2000mg/L, ibuprofen≤500mg/L, rifampicin≤60mg/L, doxycycline≤50mg/L), the relative deviation of the measurement results does not exceed ±15.0%

【Performance】

1. Limits of detection

No higher than 0.10ng/mL

2. Accuracy

The relative deviation to the target value is limited to ±15.0%.

3. Precision

The within and between assay coefficient of variations are within 15%.

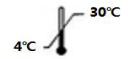
4. Linear range

Within the linear range (0.10 ~ 16.00) ng/mL, the linear correlation coefficient R⩾0.990.

【Note】

1. The kit can be used for in vitro diagnosis only.
2. Test card and buffer solution are single-use and they cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ~ 30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. Take the test card out of the aluminum foil bag and carry out experiment in 15min. Do not place it in the air for a long time to avoid dampness.
5. It is required to strictly comply with the requirements for sample collection and storage. If the sample is turbid, please centrifuge and precipitate it before use.
6. The kit used should be disposed of as latent infective material, and all samples, reagents and latent contaminants should be disinfected and disposed of according to relevant local regulations.

【Interpretation of Signs】

	Storage temperature		Single-use
	Keep in dark place	IVD	IVD Reagents
	Dampproof		Refer to the specification

【Reference】

[1] Somunkiran, A., Yavuz, T., Yucel, O. and Ozdemir, I. (2007) Anti-Mullerian hormone levels during hormonal contraception in women with polycystic ovary syndrome[J]. Eur J Obstet Gyn RB, 134, 196-201.

[2] Al-Qahtani, et al., Development of a sensitive enzyme immunoassay for Anti-Mullerian Hormone (AMH) and the evaluation of potential clinical applications in males and females [J]. Clinical Endocrinology 63(3), 267-73 (2005).

[3] Zhao Li, The establishment of the reference interval of anti-Müllerian hormone for women of childbearing age in Zhejiang [D]. Zhejiang: Zhejiang University 2014; 1-72.

【Essential information】

Registered/manufacturer name: WWHS Biotech. Inc.

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