Diagnostic Kit for Anti-mullerian Hormone (Fluorescence Immunochromatographic Assay)

Instructions for Use

INTENDED USE

This kit is applicable to in vitro quantitative detection on the content of Anti-Mullerian Hormone (AMH) in human serum/plasma/whole blood/fresh finger terminal blood samples and is mainly used for implementing auxiliary evaluation of ovarian reserve function. This kit only provides the test result of Anti-Mullerian Hormone (AMH). The obtained result should be analyzed in combination with other clinical information. It must only be used by healthcare professionals.

SUMMARY

Anti-Mullerian Hormone (AMH) is a member of transforming growth factor B superfamily. AMH is an active factor secreted by granular cells of ovarian antral follicles. It is not expressed in primordial follicle but weakly expressed in granular cells of primordial follicle. It is strongly expressed in antral follicle $\leqslant$ 4mm. However, in antral follicle>4mm, its expression gradually decreases till complete disappearance. In males, it is expressed in Sertoli cells of fetal testis at the 8th week at first, which inhibits Anti-Mullerian development. In females, Anti-Mullerian is expressed in fetal ovary at the 36th week at first, and finally develops into fallopian tube, uterus, and upper vaginal segment. AMH can regulate the function of male leydig cells. In adult females, AMH can inhibit recruitment of primordial follicle and development of antral follicle to prevent premature follicle depletion.

PRINCIPLE OF DETECTION

This kit uses the double-antibody sandwich reaction principle with high specificity and fluorescence immunochromatography to quantitatively test the Anti-Mullerian Hormone (AMH) in the human serum/plasma/whole blood/fresh finger terminal blood samples. Test strip contains anti-AMH antibody pre-immobilized on the test area (T) of the membrane and goat anti-chicken IgY antibody in the control area (C). The label pad contains pre-coated fluorescently labeled anti-AMH antibody and chicken IgY antibody. In the detection of samples, AMH antigen in the samples firstly binds to fluorescently labeled anti-AMH antibody to form an immune complex. Under the immunochromatographic effect, the complex and the sample flow in the inside nitrocellulose membrane towards the absorbent paper. The complex binds with the coated anti-AMH antibody while it passes through test area (T), to form “anti-AMH antibody-AMH antigen-fluorescence-labeled anti-AMH antibody” complex and thus aggregate. When passing through the control area (C), the fluorescently labeled chicken IgY antibody binds to the coated goat anti-chicken IgY antibody to form a "goat anti-chicken IgY antibody-fluorescently labeled chicken IgY antibody" complex and agglutinates. The AMH concentration in the sample is positively correlated with the fluorescence intensity, and the concentration of AMH in the sample can be detected by the fluorescence immune analyzer.

MAIN KIT COMPONENTS

Catalogue number	53310701	53310705	53310720	53310725
Specification / Components	1 Test/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit
Test Device(s)	1	5	20	25
Sample Diluents	1	5	20	25
Instructions for Use	1	1	1	1

MAIN ACTIVE INGREDIENTS

1. Test line (T line): T line area of nitrocellulose membrane is coated with anti-AMH antibody.
2. Control line (C line): C line area of nitrocellulose membrane is coated with Goat anti-chicken IgY antibody.
3. Labeling pad: It is coated with fluorescent-microsphere-labeled Anti-AMH antibody and Chicken IgY antibody.
4. Main component of sample diluent is 20mM, pH7.4 PBS solution.

STORAGE CONDITION

1. The kit should be stored at 2℃~30℃. The shell life of the kit is 24 months.
2. The sample diluent should be capped immediately after opening and kept in a cool place.
3. Do not use the kit after the expiration date.

APPLICABLE INSTRUMENT

The product can only be used with portable immune analyzer WIZ-A101 from WIZ BIOTECH.

SAMPLE COLLECTION AND STORAGE

1. This kit is indicated for testing of venous whole blood, serum, plasma, and fresh finger terminal blood. For whole blood and plasma samples, can use anticoagulant such as EDTA-K2, heparin, and sodium citrate.
2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedures.
3. To avoid interference with the test result, do not use hyperlipidemic, hemolytic or turbid sample.
4. Whole blood collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Whole blood shall be tested as soon as possible after collected. If test cannot be performed in time, the sample shall be stored at 2℃~8℃ for up to 2 days.
5. Serum/plasma collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Serum and plasma shall be separated as soon as possible after blood sampling to avoid hemolysis. The separated serum and plasma shall be tested immediately. If test cannot be performed in time, the separated samples can be stored at 2℃~8℃ for 7 days. If frozen below -15℃, samples can be stores for 6 months.
6. Fresh terminal blood of fingertips should be used immediately after collection.
7. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifugation or filtered to clarity.
8. Before test, sample should be in room temperature and mixed thoroughly.

REAGENT PREPARATION

1. Use immediately after open the aluminum foil bag.

2. Before test, restore the reagent to room temperature.

TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

The following operation steps are all performed provided that WIZ-A101 portable immune analyzer has been ready for use. To select or change any setting of WIZ-A101 portable immune analyzer, please refer to user manual of WIZ-A101 portable immune analyzer.

WIZ-A101 portable immune analyzer has two test modes: I standard test mode; II quick test mode. It is required to select corresponding test mode before test, and then go into the next operation:

I Select standard test mode of WIZ-A101 portable immune analyzer

I-1: Use of portable immune analyzer

(1) Open the aluminum foil bag package of reagent, and take out the test device;

(2) Horizontally insert the test device into the slot of immune analyzer;

(3) On home page of operation interface of immune analyzer, click “Standard” to enter test interface;

(4) Click “QC Scan” to scan the QR code on inner side of the kit; input kit related parameters into instrument, and select sample type;

Note: Each batch number of the kit shall be scanned for once. If the batch number has been scanned, then skip this step;

(5) Check the consistency of “Product Name”, “Batch Number” and etc. on test interface with information on the kit label;

(6) After information consistency is confirmed, take out sample diluents, add 20μL of serum/plasma/whole blood/fresh finger terminal blood sample, and sufficiently mix;

(7) Add 80μL of above mixed solution into the sample hole of test device;

(8) After complete sample addition, click “Timing” and remaining test time will be automatically displayed on the interface.

(9) Immune analyzer will automatically complete test and analysis when test time is reached.

I-2: Result calculation and display

After the test by immune analyzer is completed, test result will be displayed on test interface or can be viewed through “History” on home page of operation interface.

II Select quick test mode of WIZ-A101 portable immune analyzer

II-1: Drip the sample into the test device

(1) Open the aluminum foil bag package, take out the test device, and horizontally place it on examination table;

(2) Take out sample diluents, add 20μL of serum/plasma/whole blood/fresh finger terminal blood sample and mix;

(3) Add 80μL of above mixed solution into the sample hole of test device;

(4) Start stopwatch and wait for 15 minutes.

II-2: Use of portable immune analyzer

(1) After post-sample-addition reaction for 15 minutes, horizontally insert the test device into the slot of immune analyzer;

(2) On home page of operation interface of immune analyzer, click “Quick Test” to enter test interface;

(3) Click “QC Scan” to scan the QR code on inner side of the kit; input kit related parameters into instrument, and

select sample type;

Note: Each batch number of the kit shall be scanned for once. If the batch number has been scanned, then skip this step.

(4) Check the consistency of “Product Name”, “Batch Number” and etc. on test interface with information on the kit label;

(5) After information consistency is confirmed, click “Test”. The immune analyzer will automatically complete test and analysis.

II-3: Result calculation and display

After the test by immune analyzer is completed, results will be displayed on test interface or can be viewed through “History” on home page of operation interface.

INTERPRETATION OF THE RESULT

Gender		Range (ng/mL)
Healthy male		0.77~16.05ng/mL
Female	20~24 years old	1.28~12.01ng/mL
	25~29 years old	0.85~9.64ng/mL
	30~34 years old	0.56~8.32ng/mL
	35~39 years old	0.18~7.23ng/mL
	40~44 years old	0.10~5.73ng/mL
	45~50 years old	0.10~2.68ng/mL

1.For the reference intervals established based on the above data of test kit, it is recommended that each laboratory establish the reference intervals based on the clinical significance of the population in its region.

2. If the measured AMH concentration of the sample is higher than the range of reference value, state such as physiological change or stress reaction should be excluded. It is indeed abnormal and should be diagnosed in combination with clinical symptoms. Above result is only for reference.

3. Test result of this method is only applicable to evaluation using the reference value established in this method and cannot be directly compared with result of other method.

4. Other factors that may cause wrong test result include technical reason, operation error and other sample factors.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.
2. This kit is for healthcare professionals only.
3. Before test, restore reagent and sample to room temperature.
4. This kit is disposable.
5. Do not use expired reagent.
6. Sample collection and storage must be performed in strict accordance with this instruction.
7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.
8. Do not open the aluminum foil bags before test and protect the products from moisture; do not use if the aluminum foil bags are damaged or if the test reagents are wet.

9. For all components of the kit, it is recommended not to mix or interchange different batches.
10. Excessive or insufficient sample may lead to deviation of result.
11. Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.
12. Test method should strictly follow the instruction for use.
13. For specific explanation of test result, analysis shall be performed in combination with clinical information.
14. The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.
15. Desiccant in aluminum foil bag is inedible.
16. Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.
17. During test, test procedure, precautions and result explanation of the reagent must be followed to avoid wrong result.

PRODUCT PERFORMANCE INDEX

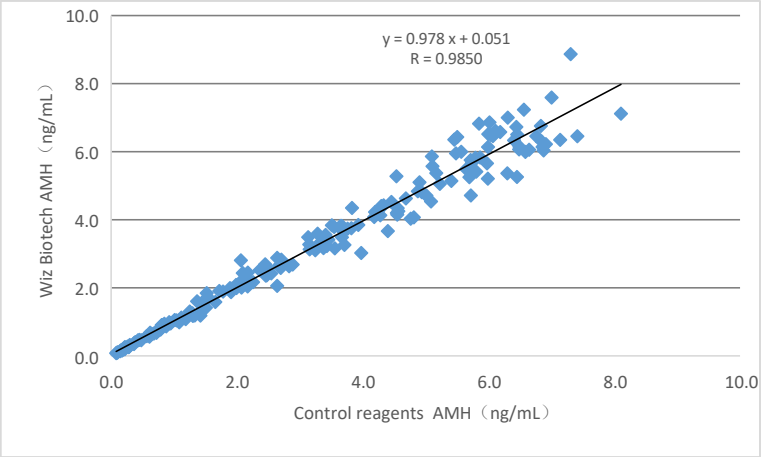
Evaluation performed using internal enterprise reference, that all performance indexes of this kit conform to standard. Specific performance indexes are as below:
1. Reportable range of the reagent (kit) is 0.1ng/mL -250ng/mL.
2. Linearity range: Linearity of the reagent (kit) is within 0.1ng/mL~25ng/mL. Analysis performance meets the following requirement:
a) Relative deviation of the determination result shall be within ±15%;
b) The correlation coefficient (r) of linearity should be≥0.9900.
3. Accuracy: The recovery rate should be within the range of [85% ~ 115%].
4. Limit of detection: ≤0.1ng/mL.
5. Repeatability: CV≤15%.
6. HOOK effect: When AMH concentration is ≤300 ng/mL, there is no HOOK effect.
7. Specificity: FSH and LH are detected under the following concentration conditions and no cross phenomenon occurs.

Material	Concentration	Material	Concentration
FSH	500mIU/mL	LH	500mIU/mL
Inhibin A	100ng/mL	Activin A	100ng/mL

8. Interfering substance: Following substances are found to cause no interference when they are tested at the given concentration.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	171μmol/L	Triglyceride	17mmol/L
Hemoglobin	2.5g/L	Rheumatoid factor	150IU/mL

9. Clinical performance
Clinical evaluation performance of the product is assessed by collecting 193 clinical samples. The results are compared by using the corresponding kit of marketed electrochemiluminescence method as the control reagent. Their comparability is studied by linear regression. The correlation coefficients of the two tests are Y=0.978X+0.051 and R=0.9850, respectively.



LIMITATION

1. This reagent is only used for testing human whole blood, serum, plasma, and fresh finger terminal blood.
2. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
3. Test shall be carried out at normal room temperature (18℃~25℃).
4. Linearity range of this kit is 0.1ng/mL~25ng/mL. To measure accurate concentration of high-concentration sample that exceeds measurement linearity range of the kit, measurement and calculation should be performed after dilution to within the linearity range of the kit. Under the conditions of normal saline or sample diluents, the maximum dilution multiple of this kit is 10 times and the reportable range is 0.1ng/mL-250ng/mL.
5. Due to low concentration of the analyte, this method cannot detect analyte, this will lead to result deviation.
6. Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
7. This test has a low probability of false positive results. Therefore, all positive results must be verified by other method.
8. If the obtained result is questionable, immediately re-test or use other method to test the sample.
9. Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.

LITERATURE REFERENCES

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[3] van Rooij IA, Broekmans FJ, te Velde ER, etc. Serum anti-Müllerian hormone levels: a novel measure of ovarian reserve. Hum Reprod. 2002;17(12):3065-3071.
[4] Meczekalski B, Czyzyk A, Kunicki M, etc. Fertility in women of late reproductive age: the role of serum anti-Müllerian hormone (AMH) levels in its assessment [published correction appears in J Endocrinol Invest. 2016 Nov;39(11):1267]. J Endocrinol Invest. 2016;39(11):1259-1265.

SYMBOLS

Symbol	interpretation	Symbol	interpretation	Symbol	interpretation

	Consult instructions for use		Tests per kit		Manufacturer
IVD	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
30℃ 2℃	Store at 2℃～30℃	REF	Catalogue number	LOT	Batch code
EC REP	Authorized Representative in the European Community		Caution		Biological risks
	Don't use the product when the package is damaged		Keep dry		

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