

(For Dry Fluorescence Immunoassay Analyzer)

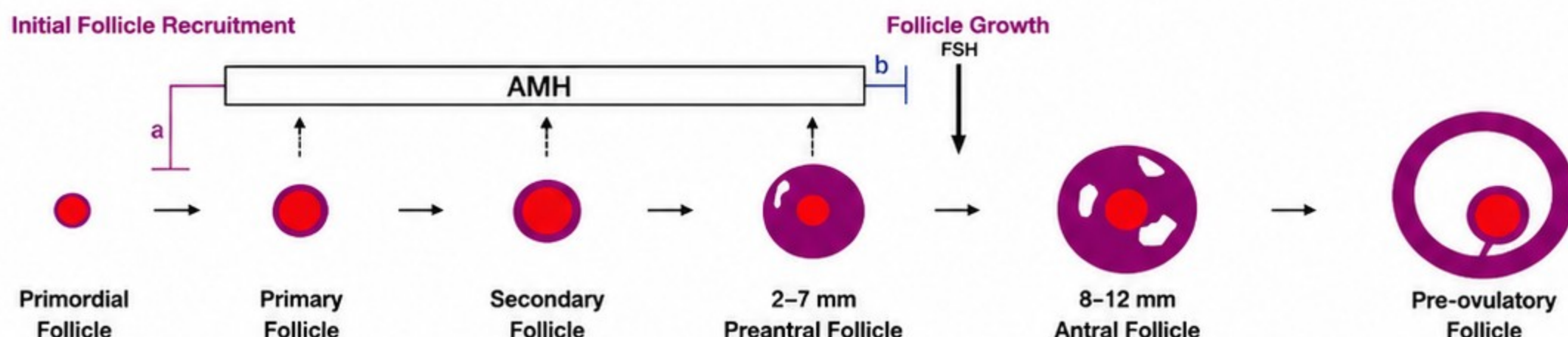
Medical Device Registration Certificate No.: 20222400393

AMH detection function clinical evaluation report

Project Introduction:

Anti-Müllerian Hormone (AMH) is a member of the transforming growth factor- β superfamily, secreted by granulosa cells of pre-antral and small antral follicles. AMH reflects the ovarian reserve of reproductive-aged women and can be used to evaluate ovarian reserve and predict the ovarian response to stimulation.

Initial Follicle Recruitment

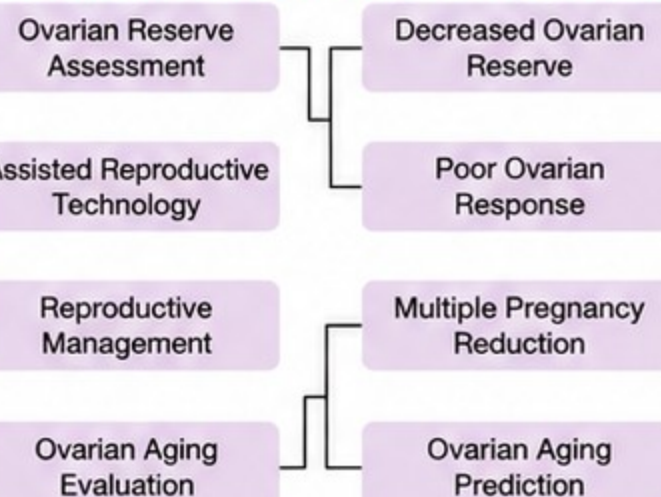


Clinical Applications of AMH:

AMH has been widely used in evaluating ovarian reserve, infertility related diseases, assisted reproductive technology, etc., and has been included in multiple clinical guidelines, such as:

- Expert Consensus on Inadequate Ovarian Response (2016)
- Chinese Guideline for the Clinical Practice of Multiple Pregnancy Reduction (2018)
- Chinese Guideline for Diagnosis and Treatment of Premature Ovarian Insufficiency (2018)
- Expert Consensus on Ovarian Low Response (2015)
- Expert Consensus on Ovarian Aging Assessment and Prediction (2015)

AMH Clinical Applications



Advantages of AMH Testing:

1. AMH is stable in serum/plasma and is not affected by menstrual cycle, and can be tested at any time;
2. AMH is not affected by exogenous gonadotropins (AFC) count errors, making it more objective, accurate, and easier to compare;
3. Not affected by the selection of ovulation-inducing drugs, facilitating clinical use.

Test Item	Testing Time	Influencing Factors	Sensitivity	Judgment Standard
Basal FSH/E2	Day 2-4 of Menstrual Cycle	Affected by intra-cycle hormone fluctuations	Low sensitivity, may fail to assess ovarian reserve accurately	Non-unified, with different standard ranges
AFC	Day 2-4 of Menstrual Cycle	Affected by intra-cycle hormone fluctuations and operator experience	High sensitivity but requires professional ultrasound operator	Different standards across hospitals
AMH	Any time	Not affected by intra-cycle hormone fluctuations	High sensitivity and can predict ovarian response changes early	Unified standard, single consistent judgment

Recommended Population for AMH Testing

Suitable population – for predicting ovarian reserve
Diseases related to ovaries – auxiliary diagnosis, screening, prognosis, evaluation of treatment or postoperative ovarian function
Clinical reproductive population – auxiliary prediction of ovarian function
Application of reproductive biotechnology in women – auxiliary selection of personalized treatment plans

Applicable Departments



Physical Examination Center



Gynecology



Obstetrics



Ofertility Clinic



Endocrinology



Pediatrics

Interpetation of AMH Reference Values

1. AMH and Related Ovarian Diseases

Related Ovarian Diseases	AMH Value
Diminished Ovarian Reserve (Decreased Ovarian Function)	AMH value is lower than the normal reference value for corresponding age
Polycystic Ovary Syndrome (PCOS)	AMH > 6.99ng/ml
Amenorrhea	AMH value is below the detection limit

2. AMH for Predicting Ovarian Response

Ovarian Response	AMH Reference Value
Poor Ovarian Response	AMH < 0.5–1.1ng/ml
Good Ovarian Response	AMH > 4.17ng/ml

3. Reference Values for Healthy Men

Age (Years)	20–60	> 60
AMH (ng/ml)	1.45–18.77	0.34–9.38

Product Parameters

Item Name [English Name]	Specimen Type and Volume	Additive	Testing Time	Linear Range	Reference Range		
					Stage	Male (ng/ml)	Female (ng/ml)
Anti-Müllerian Hormone Test Kit (AMH)	Serum, Plasma, 100µL blood (total 150µL)	Serum, Plasma Mixed sample 100µL (total mixed sample 150µL)	15 minutes	0.10ng/mL -25.00ng/mL	Pre-pubertal	>20 years	0.63–19.83
					Male	<11 years	<11.06
					Female	11–20 years	0.95–11.89
						21–30 years	0.46–11.50
						31–40 years	0.19–11.27
						41–50 years	<4.23
						>50 years	<0.34



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