



DiaSino[®] One-step sandwich Anti-Mullerian Hormone (AMH) assay

Anti-Mullerian Hormone (AMH) ELISA testing for ovarian function assessment in women



AMH Testing

Did you know

- 1 in 6 couples worldwide experience some form of **infertility**.¹
- **Polycystic ovary syndrome** (PCOS) affects **5-10% of women** of reproductive age.²
- In 30 years, the success rate of IVF has increased from 10% to above 30%.³
- At birth, women have about **2 million eggs** in their ovaries. This is the entire supply of eggs for a **lifetime**.⁴ As women age, the number of eggs suitable for a viable pregnancy **decrease** in quality and quantity.

Anti-Mullerian Hormone - AMH

Introduction

AMH plays a fundamental role in the regression of Mullerian ducts in male embryo and in its absence, Mullerian ducts develop into female inner reproductive organs. In females, it is secreted by the granulosa cells of pre-antral and small antral ovarian follicles.⁵ AMH regulates follicle recruitment and growth of small ovarian follicles while preventing exhaustion of follicular pool.^{6, 7, 8}

Serum levels of AMH correlate with the number of primordial follicles in an ovary (true ovarian reserve).^{5, 9, 10} The determination of AMH is used for the assessment of the ovarian reserve in conjunction with other clinical and laboratory findings.

Anti-Mullerian Hormone (AMH) clinical applications

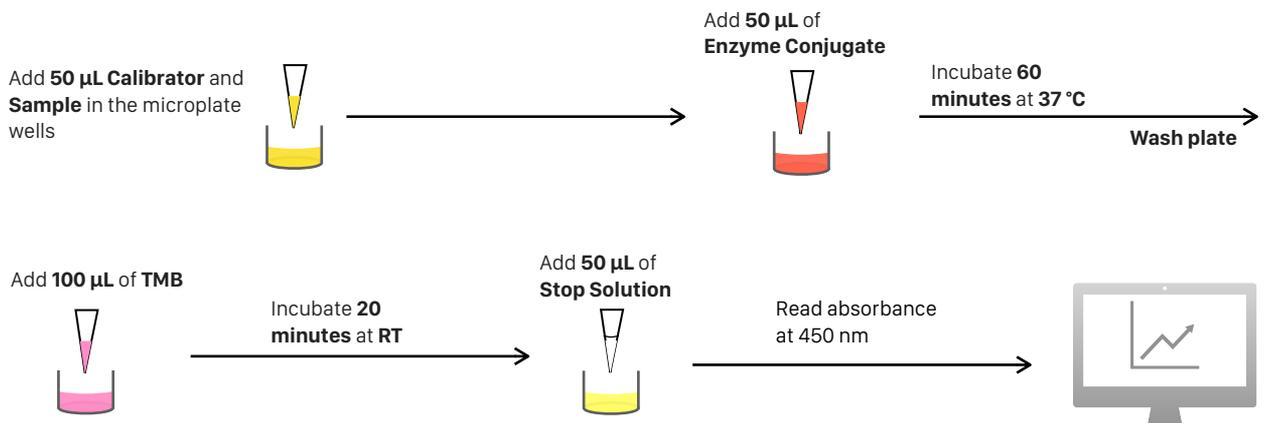
AMH is a very important and **accurate marker** of **ovarian reserve**, which could be measured by a simple blood test. Ovarian reserve test results **indicate remaining quantity of eggs** and the **remaining fertile time for a woman**.^{11, 12}

AMH is a hormone produced by the growing ovarian follicles. Blood levels of this hormone are used to measure the size of the growing **pool of eggs**. This can empower couples to make decisions about the right time to **get pregnant naturally** or to consider treatment.¹³

AMH can be used for the detection of **ovarian dysfunction**, such as **PCOS, Premature ovarian failure**, etc. The use of AMH rather than Follicle Stimulating Hormone (FSH) or Luteinizing Hormone (LH) provides direct, and more accurate assessment of ovulation.

AMH can be used for personalization of **infertility management** (IVF/ART), such as assessment of ovarian reserve for infertility investigations, and help to select the best stimulation protocol. The likelihood of response to IVF treatment

DiaSino AMH test principle: One-step sandwich assay



diasino[®]

Anti-Mullerian Hormone

- Ready to use reagents across whole kit
- Reliable results with 80 minutes testing time
- Wide measuring range
- High sensitivity/Low limit of detection
- Allows measurement at extremes of detection scale for assessment of ovarian reserve

DiaSino[®] Anti-Mullerian Hormone (AMH) test characteristics

Total duration	80 min
Assay principle	One-step sandwich
Calibrators	0, 0.5, 2.0, 5.0, 10 and 25 ng/mL
Calibration	Point to point
Sample volume	50 µL
Limit of detection	0.02 ng/mL
Measuring range	0.02 - 25 ng/mL
Traceability	Standardized against Roche Elecsys AMH
Total precision	≤10%
Sample material	Serum
High dose hook	500 ng/mL

Expected values

	N	5 th perc. ng/mL (95% Confidence interval)	Median ng/mL (95% Confidence interval)	95 th perc. ng/mL (95% Confidence interval)
Healthy men				
	207	1.37 (0.296 - 1.87)	5.01 (4.33 - 5.69)	12.5 (11.1 - 16.8)
Healthy women (years)				
20 - 24	77	1.54 (0.831 - 1.77)	4.15 (3.65 - 4.47)	9.58 (7.26 - 11.83)
25 - 29	121	1.11 (0.821 - 1.72)	3.86 (3.17 - 3.96)	9.24 (7.33 - 10.76)
30 - 34	98	0.615 (0.458 - 0.915)	2.561 (2.110 - 3.281)	7.77 (6.34 - 9.62)
35 - 39	95	0.417 (0.127 - 0.827)	1.986 (1.54 - 3.33)	6.13 (4.97 - 8.26)
40 - 44	93	0.073 (0.022 - 0.255)	0.98 (0.717 - 2.040)	3.08 (2.45 - 6.37)
45 - 50	84	0.041 (0.019 - 0.180)	0.375 (0.28 - 0.45)	1.95 (1.76 - 3.88)
PCOS women				
	177	2.56 (1.48 - 2.95)	7.01 (6.5 - 7.5)	17.41 (13.6 - 21.2)

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

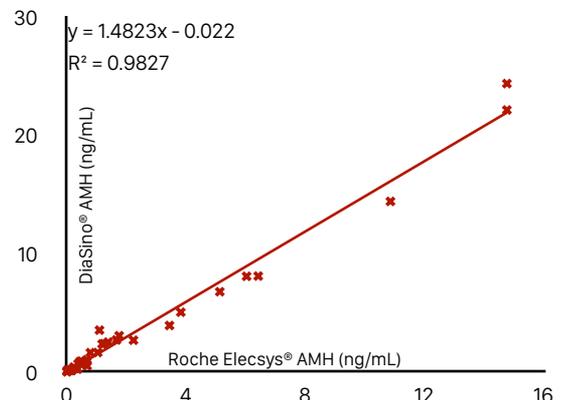
Precision

Precision was determined using DiaSino[™] AMH reagents, pooled human sera, and controls in a modified protocol (EP5-A) of the CLSI (Clinical and Laboratory Standards Institute): 2 times daily for 20 days (n = 40). The following results were obtained below.

Sample	Mean ng/mL	Repeatability (Within-run precision)		Intermediate Precision	
		SD ng/mL	CV %	SD ng/mL	CV %
Human Serum 1	0.1	0.005	5.00	0.00	8.69
Human Serum 2	0.44	0.024	5.46	0.03	6.74
Human Serum 3	3.11	0.146	4.71	0.20	6.32
PC Universal 1	1.63	0.088	5.38	0.09	5.75
PC Universal 2	7.86	0.321	4.09	0.42	5.36

Method comparison

A comparison of the DiaSino[®] AMH assay (y) with the Roche Elecsys[®] AMH (x) using clinical samples gave the following correlations:
Number of samples measured: 40



Ask your doctor about the benefits of AMH testing



Done via a simple blood test
that ordered by your doctor



No requirement for invasive
tests such as trans-vaginal
ultrasound



Helps your doctor advise you
on how to maximize your
chances of conceiving

References

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