

Clinical Pathology Laboratories

New Test Announcement

Anti-Mullerian Hormone (AMH)

Effective September 18, 2017, Clinical Pathology Laboratories will offer in-house testing for Anti-Mullerian Hormone using the Roche COBAS Elecsys Electrochemiluminescence Immunoassay.

Anti-Mullerian Hormone (AMH) is:

- a glycoprotein belonging to the transforming growth factor β (TGF- β) family that controls ovarian folliculogenesis.
- expressed in primary follicles and is maximal in granulosa cells of preantral and small antral follicles.
- relatively stable during the menstrual cycle with more fluctuation observed in younger women.
- decreased significantly under influence of certain oral contraceptives.

The Roche COBAS AMH assay is FDA approved for assessment of ovarian reserve in the management of fertility patients, correlating with ovarian antral follicle counts (AFC). An interpretive chart for the new method provides age-stratified reference ranges as follows:

Female Age Bracket (years)	AMH Reference Range (ng/mL)
20-24	1.22-11.7
25-29	0.890-9.85
30-34	0.576-8.13
35-39	0.147-7.49
40-44	0.030-5.47

In validation of the Roche Elecsys AMH assay, CPL confirmed a 40% negative bias relative to the prior method, Ansh picoAMH ELISA assay.

AMH values were correlated to the antral follicle count (AFC) in a study of 856 women presenting to fertility clinics. Patients excluded from the study included those with polycystic ovarian syndrome (PCOS), extremes of body mass, ovarian masses, ovarian surgery, endocrine disease, and oral contraceptive use. AFC was determined by transvaginal ultrasonography (TVUS), which measures antral follicles (2-10 mm) of the ovaries. Both AFC and AMH were measured and correlated on days 2-4 of the same menstrual cycle. For an AMH cutoff of 1.77 ng/mL, the performance characteristics for determination of intermediate to normal ovarian reserve (defined as AFC > 15) is as follows:

	Result
Sensitivity	68.3%
Specificity	88.3%
Positive predictive value (PPV)	75.2%
Negative predictive value (NPV)	84.3%

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Order Unit Code/Test Name:	5786 Anti-Mullerian Hormone
Test Method:	Electrochemiluminescence Immunoassay (ECLIA)
Specimen Requirements:	2 mL serum. Allow SST to clot in an upright position for at least 30 minutes, then centrifuge sample within 2 hours of collection. Refrigerate. <i>Note: Do not collect samples from patients receiving therapy with high biotin doses (>5 mg/day) until at least 8 hours following the last biotin administration</i>
Transport Temperature:	Refrigerated
Stability (collection to initiation of testing):	Ambient, 15 to 25 °C: 3 days Refrigerated, 2 to 8 °C: 5 days Frozen, -15 to -25 °C: 6 months
Performed:	Monday to Friday, Day Shift
Analytic Time:	1 day
Reference Range:	Interpretive Chart
CPT Code:	82397

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