



**Fully automated Elecsys® Anti –
Mullerian Hormone (AMH) assay**
*Providing clinical confidence in reliable
assessment of ovarian reserve*



cobas®
Life needs answers

Elecsys® AMH

Electrochemiluminescence immunoassay (ECLIA) for the in vitro quantitative determination of anti- Mullerian Hormone in human serum and plasma

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, AMH is secreted primarily by the granulosa cells of preantral and small antral follicles (i.e. growing follicles)³. These follicles can be recruited by exogenous FSH to grow to a preovulatory stage and so AMH regulates follicle recruitment and growth of small ovarian follicles while preventing exhaustion of follicular pool.^{1,2,5} Functional ovarian reserve refers to the number of growing (i.e. preantral and antral) follicles that can be recruited by exogenous FSH to grow to a preovulatory stage.⁵

Serum levels of AMH correlate with the number of primordial follicles in an ovary (true ovarian reserve).^{3,8,4} The determination of AMH is used for the assessment of the ovarian reserve in conjunction with other clinical and laboratory findings.

AMH is the marker of choice for assessment of ovarian reserve

Circulating AMH concentration is reflective of ovarian reserve and therefore the capacity to provide eggs for fertilization. Serum AMH levels have been shown to remain relatively stable during the menstrual cycle and may be measured on any day of the cycle.^{6,7}

AMH is able to distinguish between low, normal and high values related to ovarian reserve.^{2,9}

AMH assists in assessment of ovarian reserve, for example identifying in patients at risk of having diminished ovarian reserve. AMH can also add prognostic information to the counseling and planning process for infertile couples seeking treatment.¹⁰

Leading ECL technology for best-in-class performance

- Roche's highly innovative Electro-Chemiluminescence (ECL) detection technology is exclusively available for use with Elecsys, **MODULAR** and **cobas e** systems
- High precision over entire measuring range for reliable results
- Higher sensitivity for better discrimination of low, normal and high values related to ovarian reserve
- Equivalent performance between serum and plasma
- Measurement is independent of operator

Increased efficiency and result consistency

- Full automation, Short incubation times
- Equivalent performance between serum and plasma
- All fertility testing on one automated platform out of one tube with Elecsys, **MODULAR** and **cobas e** systems
- Consolidation with the leading and committed Elecsys portfolio with >90 assays available
- Consistent results across Elecsys **cobas** platforms – automated platforms for every lab size

Modular analyzers that can be adapted to individual laboratory needs

- **cobas®** modular platforms deliver individualised solutions for laboratories with different workload and testing requirements
- Different analyzer models are available to suit different workload requirements (ranging from <50 to >2,000 samples per day)
- Full workstation consolidation allows routine clinical chemistry and immunochemistry assays to be conducted on a single analyzer
- Flexible system design allows for easy system reconfiguration on-site to meet the changing needs and growth of the laboratory

Reliable assessment of ovarian reserve

Fully automated, fast, sensitive and robust measurement of AMH¹²

- Reliable results with 18 minutes testing time
- Broad measuring range
- High sensitivity/Low limit of detection
- Allows measurement at extremes of detection scale for assessment of ovarian reserve

Testing time	18 min
Measuring range	0.01 – 23 ng/mL (0.071 – 164.2 pmol/L)
LoB, LoD, LoQ*	0.007 ng/mL, (0.05 pmol/L), 0.010 ng/mL, (0.071 pmol/L), 0.030 ng/mL, (0.214 pmol/L)

* LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation (20% total error)

High precision over entire measuring range for reliable results^{11,12}

Confidence that results are reliable, consistent, reproducible, and that the assay provides a robust assessment of ovarian reserve

- Improved discrimination of low, normal and high values related to ovarian reserve
- < 5% precision (0.23 ng/mL – 1796 ng/mL)
- Minimum variability of results between users and labs
- Minimum variability of results between different analyzer platforms

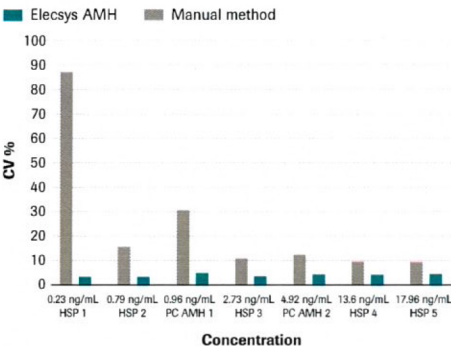


Figure 1: Precision comparison between Elecsys and a manual method on the market as part of a method comparison study conducted. The study has been run according to CLSI Protocol (CLSI-EP5)

Clinical agreement with Antral-Follicle-Count (AFC)¹²

- Providing reassurance when concordant results confirm expected level of ovarian reserve
- High agreement with AFC (Spearman's rank coefficient=0.68)
- Performed in a 7 sites multicenter evaluation
- Lower variability of results between sites and operators with AMH in comparison to AFC

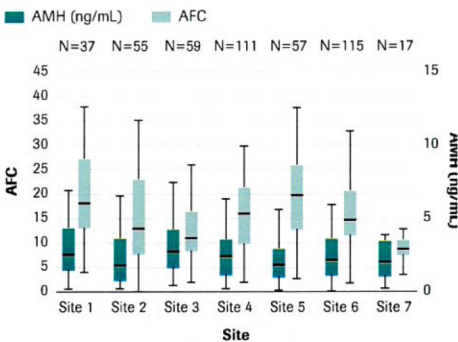


Figure 2: Distribution of AFC and AMH in 7 site multicenter evaluation. Multiple technicians performed AFC at each site

Age specific reference ranges and Polycystic ovary syndrome (PCOS) information¹²

Improved interpretation of circulating AMH and counselling of infertile patients

- Demonstrates decreased values associated with ovarian reserve during aging
- Provides values of PCOS patients

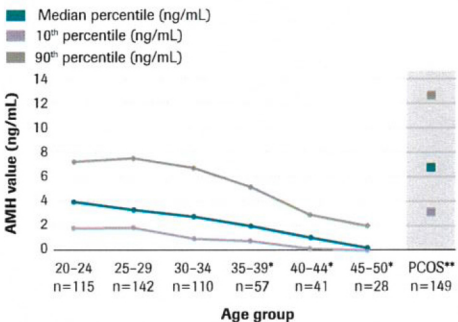


Figure 3: Elecsys AMH values of apparently healthy women per 5 years age groups and Elecsys AMH of women with diagnosed PCOS

Reliable assessment of ovarian reserve

Investigation of infertility on one platform

- Opportunity for consolidation with >230 parameters on one **cobas*** platform, including those highly relevant for fertility testing or IVF setting (fertility, Endocrinology/Thyroid testing, Infectious disease, pregnancy care)
- Multiple configurations available to meet customers' needs of throughput and space

Fertility/IVF assays on cobas e analyzers (Eleclys*)

Fertility	AMH, DHEA-S, Progesterone, Prolactin, SHBG, Testosterone, HCG +B, HCG STAT, LH, FSH, Estradiol, Adrostenedione*, 17 OH progesterone*
Thyroid Function	FT4, TSH, FT3, Anti TPO, Anti TSHR
Infectious Disease	CMV, Toxo, Hep B, Hep C, HIV, Rubella, Syphilis
Ovarian Markers	Ca 125, HE4
Bone Health	Vitamin D
... and pregnancy care	PAPP-A, free Beta HCG, sFlt-1, PlGF

* In development

Confidence in clinical decision making.

References

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