

# Elecsys® AMH Plus

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

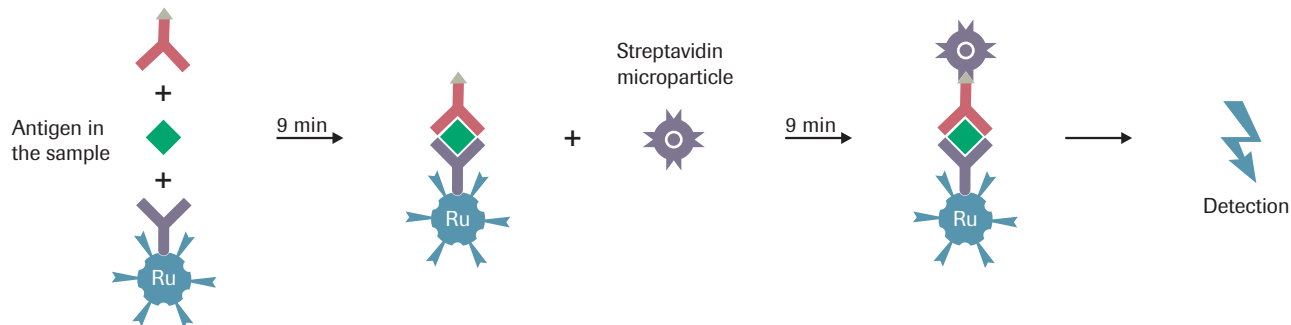
### Indication

Immunoassay for the in vitro quantitative determination of anti-Müllerian hormone (AMH) in human serum and plasma. The determination of AMH is used for the assessment of the ovarian reserve and the prediction of response to controlled ovarian stimulation (COS) in conjunction with other clinical and laboratory findings. The Elecsys AMH Plus assay may also be used, in combination with body weight, to establish the individualised daily dose of the human recombinant follicle stimulating hormone (rFSH) follitropin delta of Ferring in women undergoing an assisted reproductive technology program.<sup>1</sup>

AMH plays a fundamental role in the regression of Müllerian ducts in male embryo and in its absence, Müllerian ducts develop into female inner reproductive organs.<sup>2</sup> In females, it is secreted by the granulosa cells of pre-antral and small antral ovarian follicles. AMH regulates follicle recruitment and growth of small ovarian follicles while preventing exhaustion of follicular pool.<sup>3,4</sup>

### Test principle: Sandwich principle

Anti-AMH-Ab~Bi



Anti-AMH-Ab~Ru

#### 1<sup>st</sup> Incubation (9 minutes):

50 µL of sample, a biotinylated monoclonal mammalian AMH-specific antibody and a monoclonal mammalian AMH-specific antibody labeled with a ruthenium complex react to form a sandwich complex.

#### 2<sup>nd</sup> Incubation (9 minutes):

After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.

#### Measurement:

The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode.



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## Elecsys® technology

ECL (ElectroChemiLuminescence) is a highly sensitive detection technology used with Roche immunoassays. Based on this technology and combined with well-designed, specific and sensitive immunoassays, Elecsys delivers reliable results. The development of ECL immunoassays is based on the use of a ruthenium-complex and tripropylamine (TPA). The chemiluminescence reaction for the detection of the reaction complex is initiated by applying a voltage to the sample solution resulting in a precisely controlled reaction. ECL technology can accommodate many immunoassay principles while providing superior performance.

## Elecsys Anti-Müllerian Hormone (AMH Plus) test characteristics

Testing time	18 min
Test principle	Sandwich assay
Calibration	2 point
Traceability	Standardized against BCI AMH Gen II ELISA (unmodified)
Sample material	Serum and Li-heparin plasma
Sample volume	50 µL
LoB, LoD, LoQ*	0.049 pmol/L (0.007 ng/mL), 0.07 pmol/L (0.010 ng/mL), 0.21 pmol/L (0.030 ng/mL)
Measuring range	0.07 – 164 pmol/L (0.01 – 23 ng/mL)
Intermediate imprecision	<b>cobas e 411</b> analyzer: 2.9 – 4.4 % <b>cobas e 601/e 602</b> modules: 2.7 – 3.5 % Lowest conc. measured: 1.656 pmol/L (0.232 ng/mL)

## Expected values

	N	2.5 <sup>th</sup> perc.		5 <sup>th</sup> perc.		Median		95 <sup>th</sup> perc.		97.5 <sup>th</sup> perc.	
		pmol/L	ng/mL	pmol/L	ng/mL	pmol/L	ng/mL	pmol/L	ng/mL	pmol/L	ng/mL
<b>Healthy men</b>											
	148	5.50	0.77	10.2	1.43	34.2	4.79	82.8	11.6	103	14.5
<b>Healthy women (years)</b>											
20 – 24	150	8.71	1.22	10.9	1.52	28.6	4.00	71.0	9.95	83.6	11.7
25 – 29	150	6.35	0.890	8.57	1.20	23.6	3.31	64.6	9.05	70.3	9.85
30 – 34	138	4.11	0.576	5.08	0.711	20.0	2.81	54.2	7.59	58.0	8.13
35 – 39	138	1.05	0.147	2.89	0.405	14.2	2.00	49.7	6.96	53.5	7.49
40 – 44	142	0.193	0.027	0.421	0.059	6.29	0.882	31.7	4.44	39.1	5.47
45 – 50	169	0.071	0.010	0.071	0.010	1.39	0.194	12.8	1.79	19.3	2.71
<b>PCOS women**</b>											
	149	13.3	1.86	17.2	2.41	48.6	6.81	122	17.1	135	18.9

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

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

\*\* According to the revised diagnostic criteria of PCOS defined by the Rotterdam ESHRE/ASRM-sponsored (ESHRE = European Society of Human Reproduction and Embryology; ASRM = American Society of Reproductive Medicine) PCOS consensus workshop group<sup>5</sup>

## Order information

Elecsys AMH Plus	100 tests	07957190 190
Elecsys AMH Plus CalSet	4 x 1.0 mL	07957203 190
PreciControl AMH Plus	4 x 2.0 mL	07957211 190
Universal Diluent 2	2 x 36 mL	05192943 190

## References

- 1 Anti-Müllerian Hormone. Elecsys and cobas e analyzers package insert 2016.
- 2 La Marca, A., Broekmans, F.J. (2009). *Hum Reprod*; 24(9):2264-75.
- 3 Visser, J.A., Themmen, A.P. (2005). *Mol Cell Endocrinol*; 234(1-2):81-6.
- 4 La Marca, A., Volpe, A. (2007). *Hum Reprod Update*; 13(3):265-73.
- 5 Rotterdam ESHRE/ASRM-Sponsored PCOS consensus workshop group (2004). Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome (PCOS). *Hum Reprod*; 19(1): 41-47.

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