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.\(^1\) 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.\(^2\) 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.\(^3,4\)

**Test principle: Sandwich principle**

1st 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.

2nd 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.
Elecys® 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**:
  - LoB: 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**:
  - **cobas e 411 analyzer**: 2.9 – 4.4%
  - **cobas e 601/e 602 modules**: 2.7 – 3.5%
- **Lowest conc. measured**: 1.656 pmol/L (0.232 ng/mL)

**Expected values**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>2.5th perc.</th>
<th>5th perc.</th>
<th>Median</th>
<th>95th perc.</th>
<th>97.5th perc.</th>
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<tr>
<td></td>
<td>pmol/L</td>
<td>ng/mL</td>
<td>pmol/L</td>
<td>ng/mL</td>
<td>pmol/L</td>
<td>ng/mL</td>
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<tr>
<td>Healthy men</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>148</td>
<td>5.50</td>
<td>0.77</td>
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<td>10.2</td>
<td>1.43</td>
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<td>Healthy women (years)</td>
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<td>20 – 24</td>
<td>150</td>
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<td>1.22</td>
<td>10.9</td>
<td>1.52</td>
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<td>25 – 29</td>
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<td>0.711</td>
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<td>40 – 44</td>
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<td>0.027</td>
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<td>45 – 50</td>
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<td>0.071</td>
<td>0.010</td>
<td>0.071</td>
<td>0.010</td>
<td>1.39</td>
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<tr>
<td>PCOS women**</td>
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<td>149</td>
<td>13.3</td>
<td>1.86</td>
<td>17.2</td>
<td>2.41</td>
<td>48.6</td>
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</table>

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

**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**


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