Mullerian-Duct Repression Hormone ELISA (MRH/AMH) ELISA

- High precision in clinically relevant measurement ranges
- Very good correlation \((R^2=0.96)\) with AMH Gen II ELISA (Beckman Coulter)
- Fully automated test performance possible

Technical data

**Coating**: Highly purified MRH* antibody

**Calibration**: Quantitative, in nanogrammes per milliliter (ng/ml), 6 calibrators

**Sample material**: Serum or heparin plasma, undiluted

**Reagents**: Ready for use, with the exception of the wash buffer (10x), calibrators and controls (lyophilised); colour-coded solutions

**Test procedure**: 90 min / 60 min / 30 min / 15 min (samples / biotin / conjugate / substrate incubation), room temperature, fully automatable

**Measurement**: 450 nm, reference wavelength between 620 nm and 650 nm

**Test kit format**: 96 break-off wells; kit includes all reagents

**Order no.**: EQ 6161-9601

Clinical significance

The Mullerian-duct repression hormone (MRH), also known as anti-Mullerian hormone (AMH), is a glycoprotein from the transforming growth factor (TGF) \(\beta\) family. TGF-\(\beta\) has an important function in cell differentiation and cell proliferation. In male zygotes MRH causes regression of the Mullerian ducts, which otherwise develop into the uterus, oviducts and ovaries. MRH plays a decisive role in the development of the male genitals. In men the peptide hormone is produced in the Sertoli cells of the testis. In women, MRH is secreted in the granulosa cells of preantral and small antral follicles from puberty. Here it plays a central role in follicle recruitment and selection. At the same time it inhibits the transformation of primordial follicles into maturation stages and thus delays depletion of the follicle pool.

The serum concentration of the hormone correlates with ovarian function and shows only a relatively small cycle-dependent variability. The MRH level in women falls with increasing age, corresponding to the loss of ovarian reserve. Measurement of the MRH concentration can be useful for the assessment of the response rate to ovarian stimulation during fertility treatment. With a limited ovarian function reserve the values are decreased compared to age-dependent normal values, indicating an increased need in gonadotropins for follicle stimulation. An increased MRH level can be an indicator of polycystic ovarian syndrome. In addition to fertility assessment, measurement of the MRH concentration is also relevant for the diagnosis of other diseases, e.g. in the differential diagnosis of gonadal dysgenesis or as tumour marker in granulosa cell tumours.

Diagnostic application

The EUROMMUN Mullerian-Duct Repression Hormone (MRH/AMH) ELISA is based on a novel combination of two highly specific antibodies. It provides precise results in clinically relevant measurement ranges and a high reproducibility owing to lyophilised calibrators and controls.

*Anti-Mullerian hormone (AMH)*
**Detection limit**

The lower detection limit is defined as the mean value of an analyte-free sample plus twice the standard deviation (confidence level 95%) and is the smallest clearly detectable MRH concentration. The lower detection limit of the MRH/AMH ELISA is 0.07 ng/ml.

**Linearity**

The linearity was determined by diluting 3 serum samples (17 to 283 ng/ml) to a final dilution of 1:640 with sample buffer. The mean concordance with respect to the expected value was 99% (83 to 110%), with a mean correlation coefficient of $r = 0.997$.

**Normal values**

The normal values in women were determined by investigating 85 serum samples from women aged 20 to 90 years. The mean values of the different age groups are shown in the adjacent illustration.

The investigation of 61 serum samples from men between 18 and 80 years of age yielded the following normal values: men between 18 and 45 years: 4.52 ng/ml, men between 46 and 80 years: 3.02 ng/ml.

Every laboratory should use their own normal values established under specific ambient conditions.

**Correlation**

The EUROIMMUN ELISA was compared to the commercial AMH Gen II ELISA from Beckman Coulter by measuring the MRH concentrations in 88 serum samples from female patients. The linear regression analysis yielded a good correlation between the competitive test systems ($R^2 = 0.9562$).

**Interference**

Haemolytic, lipaemic and icteric samples showed no influence on the result up to a concentration of 10 mg/ml for haemoglobin, 20 mg/ml for triglycerides and 0.4 mg/ml for bilirubin in this ELISA.

**Cross reactivity**

The EUROIMMUN ELISA specifically detects the Mullerian-duct repression hormone (MRH'). Cross reactions with other related compounds have not been found.

<table>
<thead>
<tr>
<th>Protein</th>
<th>Used up to</th>
<th>Cross reactivity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LH</td>
<td>200 IU/ml</td>
<td>0%</td>
</tr>
<tr>
<td>FSH</td>
<td>100 IU/ml</td>
<td>0%</td>
</tr>
<tr>
<td>TGF-β2</td>
<td>200 nmol/l (5 µg/ml)</td>
<td>0%</td>
</tr>
<tr>
<td>Activin A</td>
<td>1 µg/ml</td>
<td>0%</td>
</tr>
<tr>
<td>Activin B</td>
<td>1 µg/ml</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Anti-Mullerian hormone (AMH)*