Overview

Useful For
Assessment of menopausal status, including premature ovarian failure
Assessing ovarian status, including ovarian reserve and ovarian responsiveness, as part of an evaluation for infertility and assisted reproduction protocols such as in vitro fertilization
Assessing ovarian function in patients with polycystic ovarian syndrome
Evaluation of infants with ambiguous genitalia and other intersex conditions
Evaluating testicular function in infants and children
Monitoring patients with antimullerian hormone-secreting ovarian granulosa cell tumors

Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Collection Container/Tube:
Preferred: Red top
Acceptable: Serum gel

Submission Container/Tube: Plastic screw-top vial

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a General Request (T239) with the specimen.

Specimen Minimum Volume
0.1 mL

Reject Due To

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject-acceptable to 2,000 mg/dL</td>
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<tr>
<td>Gross lipemia</td>
<td>OK</td>
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</table>
Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
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<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
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Clinical and Interpretive

Clinical Information

Antimullerian hormone (AMH), also known as mullerian-inhibiting substance, is a dimeric glycoprotein hormone belonging to the transforming growth factor-beta family. It is produced by Sertoli cells of the testis in males and by ovarian granulosa cells in females. Expression during male fetal development prevents the mullerian ducts from developing into the uterus, resulting in development of the male reproductive tract. In the absence of AMH, the mullerian ducts and structures develop into the female reproductive tract. AMH serum concentrations are elevated in males under 2 years old and then progressively decrease until puberty, when there is a sharp decline. In females, AMH is produced by the granulosa cells of small growing follicles from the 36th week of gestation onwards until menopause when levels become undetectable.

Because of the gender differences in AMH concentrations, its changes in circulating concentrations with sexual development, and its specificity for Sertoli and granulosa cells, measurement of AMH has utility in the assessment of gender, gonadal function, fertility, and as a gonadal tumor marker. Since AMH is produced continuously in the granulosa cells of small follicles during the menstrual cycle, it is superior to the episodically released gonadotropins and ovarian steroids as a marker of ovarian reserve. Furthermore, AMH concentrations are unaffected by pregnancy or use of oral or vaginal estrogen- or progestin-based contraceptives.

Studies in fertility clinics have shown that females with higher concentrations of AMH have a better response to ovarian stimulation and tend to produce more retrievable oocytes than females with low or undetectable AMH. Females at risk of ovarian hyperstimulation syndrome after gonadotropin administration can have significantly elevated AMH concentrations. Polycystic ovarian syndrome can elevate serum AMH concentrations because it is associated with the presence of large numbers of small follicles.

AMH measurements are commonly used to evaluate testicular presence and function in infants with intersex conditions or ambiguous genitalia, and to distinguish between cryptorchidism (testicles present but not palpable) and anorchia (testicles absent) in males. In minimally virilized phenotypic females, AMH helps differentiate between gonadal and nongonadal causes of virilization.

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Serum AMH concentrations are increased in some patients with ovarian granulosa cell tumors, which comprise approximately 10% of ovarian tumors. AMH, along with related tests including inhibin A and B (INHA / Inhibin A, Tumor Marker, Serum; INHB / Inhibin B, Serum; INHAB / Inhibin A and B, Tumor Marker, Serum), estradiol (EEST / Estradiol, Serum), and CA-125 (CA25 / Cancer Antigen 125 [CA 125], Serum), can be useful for diagnosing and monitoring these patients.

Reference Values

Males
Test Definition: AMH
Antimullerian Hormone, S

<24 months: 14-466 ng/mL
24 months-12 years: 7.4-243 ng/mL
>12 years: 0.7-19 ng/mL

Females
<24 months: <4.7 ng/mL
24 months-12 years: <8.8 ng/mL
13-45 years: 0.9-9.5 ng/mL
>45 years: <1.0 ng/mL

**Interpretation**

Menopausal women or women with premature ovarian failure of any cause, including after cancer chemotherapy, have very low antimullerian hormone (AMH) levels, often below the current assay detection limit of 0.1 ng/mL.

While the optimal AMH concentrations for predicting response to in vitro fertilization are still being established, it is accepted that AMH concentrations in the perimenopausal to menopausal range indicate minimal to absent ovarian reserve. Depending on patient age, ovarian stimulation is likely to fail in such patients. By contrast, if serum AMH concentrations exceed 3 ng/mL, hyper-response to ovarian stimulation may result. For these patients, a minimal stimulation would be recommended.

In patients with polycystic ovarian syndrome, AMH concentrations may be 2- to 5-fold higher than age-appropriate reference range values. Such high levels predict anovulatory and irregular cycles.

In children with intersex conditions, an AMH result above the normal female range is predictive of the presence of testicular tissue, while an undetectable value suggests its absence.

In boys with cryptorchidism, a measurable AMH concentration is predictive of undescended testes, while an undetectable value is highly suggestive of anorchia or functional failure of the abnormally sited gonad.

Granulosa cell tumors of the ovary may secrete AMH, inhibin A, and inhibin B. Elevated levels of any of these markers can indicate the presence of such a neoplasm in a woman with an ovarian mass. Levels should fall with successful treatment. Rising levels indicate tumor recurrence or progression.

**Cautions**

Like all laboratory tests, antimullerian hormone (AMH) measurement alone is seldom sufficient for diagnosis and results should be interpreted in the light of clinical findings and other relevant test results, such as ovarian ultrasonography (antral follicle count for fertility evaluation), abdominal or testicular ultrasound (intersex and testicular function applications) and measurements of sex steroids (estradiol, testosterone, progesterone), follicle-stimulating hormone (FSH), inhibin B (for fertility), and inhibin A and B (for tumor workup).

Elevated AMH is not specific for malignancy, and the assay should not be used exclusively to diagnose or exclude an AMH-secreting ovarian tumor.

This assay demonstrates no cross reactivity with, Inhibin A, Inhibin B, Activin A, or Activin B at concentrations of approximately 1000 pg/mL.
As with other immunoassays, the AMH assay can be susceptible to false-low results at extremely high analyte concentrations (hooking effect).

Heterophilic antibody interferences that are not blocked by the assay's blocking regents may also rarely occur, typically false-high results. If test results are inconsistent with the clinical picture, the laboratory should be contacted.

**Clinical Reference**


**Performance**

**Method Description**

The Ansh Ultra-Sensitive Anti-Mullerian hormone (AMH) enzyme linked immunoassay (ELISA) is a quantitative 3-step sandwich immunoassay. Samples, controls, and calibrators are added to AMH antibody-coated microtiter wells and incubated. After incubation and washing, biotinylated AMH antibody solution is added. After the second incubation and washing, the wells are incubated with streptavidin horseradish peroxidase conjugate (SHRP). After the third incubation and washing, the wells are incubated with the substrate tetramethylbenzidine (TMB) followed by an acidic stopping solution. Dual wavelength absorbance measurement at 450 nm and 630 nm is directly proportional to the concentration of AMH in the sample.(Package insert: Ansh Labs Ultra-Sensitive AMH/MIS; document AL-105; revision No.04)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Monday, Wednesday, Friday

**Analytic Time**

1 day

**Maximum Laboratory Time**

4 days

**Specimen Retention Time**

3 months

**Performing Laboratory Location**

Rochester

**Fees and Codes**

**Fees**

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.
Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
83520

LOINC® Information

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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