Test Definition: AMH1

Antimullerian Hormone, S

Overview

Useful For

Assessing ovarian status, including ovarian reserve and ovarian responsiveness, as part of an evaluation for infertility and assisted reproduction protocols

Assessment of menopausal status, including premature ovarian failure

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

Highlights

Antimullerian hormone (AMH) is produced by Sertoli cells of the testis in males and by ovarian granulosa cells in females.

In female individuals, AMH is used as a marker for ovarian reserve and in the assessment of ovarian responsiveness as part of evaluation of infertility and in assistance with reproductive therapy.

In male individuals, AMH is used in the evaluation of disorders of sexual development and male fertility.

Method Name

Electrochemiluminescent Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation: For 12 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Forms

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

Specimen Minimum Volume

0.75 mL

Reject Due To

Gross hemolysis	Reject-acceptable to 1000 mg/dL
Gross lipemia	OK
Gross icterus	Reject-acceptable to 66 mg/dL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	180 days	
	Ambient	7 days	

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, serum AMH concentrations are very low at birth, peaking after puberty, decrease progressively thereafter with age, and become undetectable at menopause.

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.

In females, AMH is considered an ovarian reserve marker. It correlates with the primordial follicle pool, has an inverse correlation with chronologic age, predicts ovarian response in assisted reproductive therapy, and has been suggested to be predictive of the timing of the onset of menopause. In contrast to other markers of ovarian reserve that show significant fluctuations during the menstrual cycle, serum AMH concentrations have been shown to be relatively stable. 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 and anorchia in males.

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 cancer antigen 125 (CA25 / Cancer Antigen 125 [CA 125], Serum), can be useful for diagnosing and monitoring these patients.

Reference Values

Males

<2 years: 18-283 ng/mL

2-12 years: 8.9-109 ng/mL

>12 years: <13 ng/mL

Females

<3 years: 0.11-4.2 ng/mL

3-6 years: 0.21-4.9 ng/mL

7-11 years: 0.36-5.9 ng/mL

12-14 years: 0.49-6.9 ng/mL

15-19 years: 0.62-7.8 ng/mL

20-24 years: 1.2-12 ng/mL

25-29 years: 0.89-9.9 ng/mL

30-34 years: 0.58-8.1 ng/mL

35-39 years: 0.15-7.5 ng/mL

40-44 years: 0.03-5.5 ng/mL

45-50 years: <2.6 ng/mL

51-55 years: <0.88 ng/mL

>55 years: <0.03 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.

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.

AMH may be used as a surrogate to antral follicle count (AFC) at day 2 to 4 of the menstrual cycle to determine

ovarian reserve. Women with an AFC greater than 15 are identified as having high ovarian reserve. In this context a Roche AMH concentration greater than 1.77 ng/mL at day 2 to 4 of the menstrual cycle, identified women with an AFC greater than 15 with 88.3% sensitivity and 68.3% specificity.(1)

Controlled ovarian stimulation (COS) with exogenousgonadotropin is an essential step of in-vitro fertilization (IVF)protocols. Using the Roche AMH assay, a cut-off of 2.10 ng/mL is correlated with the response categories in women undergoing COS using a gonadotropin-releasing hormone antagonist protocol. A 2.10 ng/mL cutoff provided reliable prediction of hyper-response to COS(2). Sensitivity for the detection of hyperresponsive individuals was 81.3%, and the negative predictive value for ruling out hyperresponse was 96.6%. The 2.10 ng/mL cutoff identified 88.9% of patients with a poor response.(2)

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 suspected of cryptorchidism, a measurable AMH concentration is predictive of undescended testes, while an undetectable value is highly suggestive of anorchia or functional failure.

Klinefelter syndrome is characterized by accelerated germ cell depletion and occurs in approximately 10% to 12% of men presenting with nonobstructive azoospermia. In these patients, serum AMH concentrations are within the reference interval until puberty and thereafter, AMH concentrations decline to abnormally low or undetectable.

Pubertal delay and congenital hypogonadotropic hypogonadism (HH) share the same clinical manifestation of delayed sexual maturation in prepubertal boys. Levels of gonadotropin and testosterone are very low in prepubertal boys and therefore have little clinical significance; thus, AMH measurements are useful in the differential diagnosis of pubertal delay and congenital HH. In patients with congenital HH, AMH concentrations are abnormally low; while in pubertal delay AMH concentrations will be within the prepubertal reference interval.

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

Interference was observed at biotin concentrations above 30 ng/mL. Samples should not be taken from patients receiving therapy with high biotin doses until at least 12 hours following the last biotin administration.

The following drugs may interfere with this test: Cetrotide, Ovitrelle, Endometrin and Follistatin: do not use this test to analyze samples from patients who have received 1 or more of these products within 1 to 2 weeks of testing.

There is no high-dose hook effect at AMH concentrations up to 1400 ng/mL.

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. The laboratory should be alerted if the result does not correlate with the clinical presentation.

For diagnostic purposes, the results should always be assessed in conjunction with the patientâ€™s medical history, clinical examination and other findings.

AMH immunoassays are not standardized and values obtained with different assay methods or kits may be different and cannot be used interchangeably.

If using as a tumor marker, test results cannot be interpreted as absolute evidence for the presence or absence of malignant disease.

Clinical Reference

1. Jacobs MH, Reuter LM, Baker VL, et al: A multicentre evaluation of the Elecsys anti-Mullerian hormone immunoassay for prediction of antral follicle count. Reprod Biomed Online. 2019 May;38(5):845-852

2. Anckaert E, Denk B, He Y, Torrance HL, Broekmans F, Hund M: Evaluation of the Elecsys anti-Mullerian hormone assay for the prediction of hyper-response to controlled ovarian stimulation with a gonadotrophin-releasing hormone antagonist protocol. Eur J Obstet Gynecol Reprod Biol. 2019 May;236:133-138

3. Bedenk J, Vrtacnik-Bokal E, Virant-Klun I: The role of anti-Mullerian hormone (AMH) in ovarian disease and infertility. J Assist Reprod Genet. 2020 Jan;37(1):89-100

4. Xu HY, Zhang HX, Xiao Z, Qiao J, Li R: Regulation of anti-Mullerian hormone (AMH) in males and the associations of serum AMH with the disorders of male fertility. Asian J Androl. 2019 Mar-Apr;21(2):109-114

5. Grinspon RP, Bergada I, Rey RA: Male hypogonadism and disorders of sex development. Front Endocrinol (Lausanne). 2020 April15;11:211

Performance

Method Description

The Roche Elecsys AMH (anti-mullerian hormone) assay is a 2-site immunometric sandwich assay using electrochemiluminescence detection. Patient specimen, biotinylated monoclonal AMH-specific antibody, and monoclonal AMH-specific antibody labeled with a ruthenium react to form a complex. Streptavidin-coated microparticles act as the solid phase to which the complex becomes bound. Voltage is applied to the electrode inducing a chemiluminescent emission from the ruthenium, which is then measured against a calibration curve to determine the amount of AMH in the patient specimen.(Package insert: Elecsys AMH, Roche Diagnostics; 2.0 English 04/2020)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 3 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 has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

83520

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
AMH1	Antimullerian Hormone, S	83104-0

Result ID	Test Result Name	Result LOINC Value
AMH1	Antimullerian Hormone, S	83104-0