ACCESS AMH

HELPING FERTILITY PATIENTS PLAN FOR THE FAMILY THEY DESIRE

AMH Biology and Physiology

Anti-Müllerian hormone (AMH) is a glycoprotein belonging to the transforming growth factor-β family. AMH was named for its first-described function in fetal sex differentiation: a regression of the Müllerian ducts during early male fetal life.

In males, AMH is secreted by Sertoli cells of the testes. AMH concentrations are high until puberty, and then decrease slowly to residual post-puberty levels.

In females, AMH is produced by granulosa cells of the preantral and small antral ovarian follicles until menopause. AMH concentrations reflect the number of small follicles entering the growth phases of their life cycles, which is indicative of the number of primordial follicles that still remain in the ovary, or the ovarian reserve. In the early development of the female fetus, the absence of AMH allows the Müllerian ducts to further develop, resulting in the internal female anatomy.

Measurement of AMH

AMH has been used in the evaluation of ovarian reserve primarily to predict an infertile woman's response to controlled ovarian stimulation.

AMH decreases throughout a woman's reproductive life, which reflects the continuous decline of the oocyte/follicle pool with age and, accordingly, ovarian aging. Although AMH concentrations decrease with age, studies have shown that the day-to-day variability of AMH concentrations in menstruating women is low.

Partnering today for a stronger tomorrow

Patients need accurate, timely results for assessing ovarian reserve. For over 18 years, Beckman Coulter AMH assays have been studied extensively to establish the acceptance of AMH in the field of fertility. Partner with Beckman Coulter, the market innovator who developed the first ELISA and launched the first automated AMH assay globally, so you can help fertility patients plan for the family they desire.

The Access AMH assay will:

- Deliver patient results quickly through fast, consistent automated testing
- Present consistent and dependable results, provided by the only automated AMH immunoassay to use a recombinant human antigen
- Reduce laboratory costs by 16% over typical manual tests for assessing ovarian reserve

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Method correlations

The Access AMH assay provides consistent results through calibration to the AMH Gen II assay.* In a method comparison study using 93 serum samples in the critical range of 0.16–10 ng/mL (1.1–71 pmol/L), the automated Access AMH assay and the manual AMH Gen II assay had an excellent correlation with an r value of 0.99 and slope of 0.95.

Access AMH (Ref B13127) vs. Gen II AMH (Ref A79765)					
n	Range of Observations (ng/mL)	Intercept (ng/mL)	Slope (95% CI)	Correlation Coefficient (r)	Bias
93	0.16–9.88	0.09	0.95 (0.92–0.97)	0.99	4.0%

Method correlations to ELISA assays in individual laboratories may differ based on variables such as incubation times, pipetting technique, temperature, shaker speed, reagent lot, number and integrity of samples tested, etc.

A comparison of 121 values across the range of the assay using the Access AMH assay on the Access 2 Immunoassay system and a commercially available immunoassay kit gave the following statistical data using Passing Bablok regression and Spearman correlation for the r calculation.

Access AMH (Ref B13127) vs. Commercially Available Immunoassay				
n	Range of Observations (ng/mL)	Intercept (ng/mL)	Slope (95% CI)	Correlation Coefficient (r)
121	0.070–22.80	0.04	1.03 (1.01–1.06)	0.99

Assay sensitivity

The Access AMH assay was designed to have excellent sensitivity with a limit of detection (LoD) of ≤0.02 ng/mL (0.14 pmol/L) and a limit of quantitation (LoQ) of ≤0.08 ng/mL (0.57 pmol/L). In two separate studies, a protocol based on CLSI EP17-A2 demonstrated a LoD for Access AMH of 0.0098 ng/mL (0.07 pmol/L) and a LoQ of Access AMH of 0.013 ng/mL (0.093 pmol/L).

Characteristics

Sample Type/Size	Serum or plasma (lithium heparin)/20 µL (dispense), 25 µL (uptake)
Approximate Calibrator Levels	0, 0.16, 0.6, 4, 10 and 24 ng/mL (0, 1.1, 4.3, 29, 71 and 171 pmol/L)
Reportable Measuring Range	≤0.08–24 ng/mL (0.57–171 pmol/L)
Limit of Detection (LoD)	≤0.02 ng/mL (0.14 pmol/L)
20% CV Limit of Quantitation (LoQ)	≤0.08 ng/mL (0.57 pmol/L)
Precision	Total imprecision ≤10.0% CV at concentrations ≥0.16 ng/mL (1.1 pmol/L), and standard deviation (SD) ≤0.032 ng/mL (0.23 pmol/L) at concentrations <0.16 ng/mL
Open Pack Stability	31 days
Open Calibrator Stability	90 days
Calibration Curve Stability	31 days
Time to First Result	40 minutes (approximate)

Ordering information

Access AMH (2 packs of 50 tests/pack)	**B13127**
Access AMH Calibrators (S0–S5, 1 vial/level, 2.0 mL/vial)	**B13128**
Access AMH Controls (3 levels, 2 vial/level, 2.0 mL/vial)	**B13129**

BECKMAN COULTER OFFERS A FULL LINE OF ASSAYS TO MEET LABORATORY TESTING NEEDS, INCLUDING A BROAD REPRODUCTIVE PORTFOLIO

- AMH
- DHEA-S
- Sensitive Estradiol
- hFSH
- hLH
- Inhibin A
- Progesterone
- Prolactin
- SHBG
- Testosterone
- Total βhCG (5th IS)
- Unconjugated Estriol

Research use only (RUO)

- Inhibin B Gen II ELISA (RUO)
- PAPP-A (RUO)

Access reproductive solutions are part of a comprehensive assay menu featured on Access and UniCel Immunoassay systems. To learn more, visit **www.beckmancoulter.com/reproductive.**

*AMH Gen II was not marketed as an IVD product in the United States.

For Beckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact

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