

ACCESS AMH

DIAGNOSTIC CONFIDENCE WITH AUTOMATED ACCESS AMH TESTING



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 the early development of the female fetus, the absence of AMH allows the Müllerian ducts to further develop, resulting in the internal female anatomy. 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 phase of their life cycle, which is indicative of the number of primordial follicles that still remain in the ovary, or the ovarian reserve.

MEASUREMENT OF AMH

When AMH assays were first introduced, the primary utility was to evaluate pediatric disorders such as male testicular function, ambiguous genitalia, and precocious or delayed puberty. Additionally in females, AMH was used to monitor granulosa cell tumors of the ovary. Over the last decade, the most significant use of AMH measurement has been in the evaluation of ovarian reserve to predict response to controlled ovarian stimulation in women with infertility issues.

Research studies have also demonstrated that AMH may be used to estimate the time to menopause for an individual woman, as AMH has been found to be a good indicator of reproductive aging. Additionally, studies have shown that the use of AMH may be useful in the diagnosis and monitoring of polycystic ovary syndrome.

HOW ACCESS AMH MOVES THE LAB FORWARD

- › **Consistent and standardized results** with AMH Gen II through the use of identical antibodies and calibration.
- › **Improved support of fertility assessment** through increased sensitivity and precision at the low end of the analytical measuring range.
- › **Improved accuracy of patient results** from calibrators prepared with recombinant human AMH.
- › **Efficient and cost-effective results** with less technician handling time and increased ease-of-use compared to manual assays.
- › **Speed and flexibility** through fully-automated instrumentation.
- › **Increased stability** from lyophilized calibrators.

METHOD CORRELATION

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.

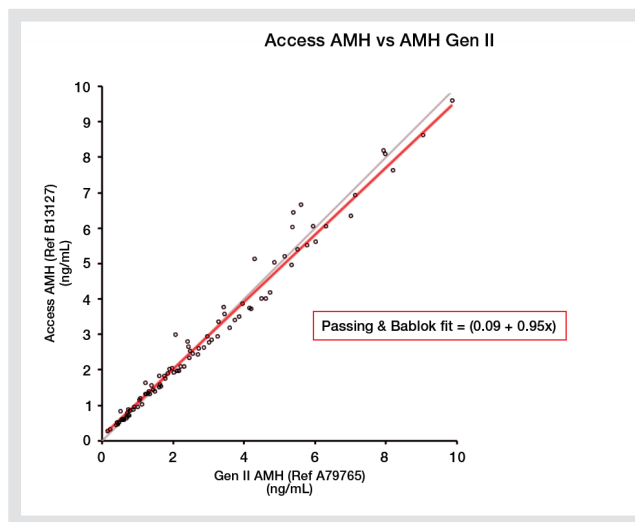
Access AMH (Ref B13127) vs Gen II AMH (Ref A79765)					
n	Range of Observations (ng/mL)	Intercept (ng/mL)	Slope (95% CI)	Correlation Coefficient (r)	Bias
93	0.16 to 9.88	0.09	0.95 (0.92 to 0.97)	0.99	4.0%

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 0.0049 ng/mL (0.035 pmol/L) and a LoQ of Access AMH of 0.010 ng/mL (0.071 pmol/L).

CHARACTERISTICS

Sample Type/Size	Serum or plasma (lithium heparin)/20 μ L
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	$\leq 0.02 - 24$ ng/mL (0.14 - 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 $\leq 10.0\%$ 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

LAB FORWARD > ACCESS REPRODUCTIVE: A MENU THAT MATTERS

AFP (ONTD)	hFSH	PAPP-A	Prolactin	Testosterone
DHEA-S	hLH	PIGF*	sFlt-1*	Total β hCG (5th IS)
Estradiol	Inhibin A	Progesterone	SHBG	Unconjugated Estriol

*In development

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.

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