BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

Access AMH
Anti-Müllerian hormone (AMH)

REF B13127

FOR PROFESSIONAL USE ONLY

Rx Only

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The Access AMH assay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of anti-Müllerian hormone (AMH) levels in human serum and lithium heparin plasma using the Access Immunoassay Systems as an aid in the assessment of ovarian reserve in women presenting to fertility clinics. This system is intended to distinguish between women presenting with AFC (antral follicle count) values > 15 (high ovarian reserve) and women with AFC values ≤ 15 (normal or diminished ovarian reserve). The Access AMH is intended to be used in conjunction with other clinical and laboratory findings such as antral follicle count, before starting fertility therapy. The Access AMH is not intended to be used for monitoring of women undergoing controlled ovarian stimulation in an Assisted Reproduction Technology program.

SUMMARY AND EXPLANATION

Anti-Müllerian hormone (AMH) is a glycoprotein, which circulates as a dimer composed of two identical 72 kDa monomers that are linked by disulfide bridges. AMH belongs to the transforming growth factor-β family.[1,2]

AMH is named for its first described function in fetal sexual differentiation: a regression of the Müllerian ducts in males during early 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.[3] This decline of AMH production during puberty is related to the pubertal development stage.[4]

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.[5] In females, AMH expression has been observed at approximately 36 weeks gestation in granulosa cells of preantral ovarian follicles and is produced by these cells until menopause.[6,7]

AMH concentrations in adult women reflect the number of small antral and preantral follicles entering the growth phase of their life cycle, which is proportional to the number of primordial follicles that still remain in the ovary, or the ovarian reserve.[5,8,9] AMH decreases throughout a woman's reproductive life, which reflects the continuous decline of

the oocyte/follicle pool with age and, accordingly, ovarian aging.[10] Although AMH concentrations decrease with age, studies have shown that the day-to-day variability of AMH concentrations in menstruating women is low.[11] AMH has been used in the evaluation of ovarian reserve.[12]

METHODOLOGY

The Access AMH assay is a simultaneous one-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel, along with a mouse monoclonal anti-AMH antibody conjugated to alkaline phosphatase in MES buffer, TRIS buffered saline with proteins, and paramagnetic particles coated with a mouse monoclonal anti-AMH antibody in TRIS buffer. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by this reaction is measured with a luminometer. The light production is directly proportional to the concentration of AMH in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

SPECIMEN

SPECIMEN COLLECTION AND PREPARATION

1. Serum and plasma (lithium heparin) are the recommended samples.
2. Observe the following recommendations for handling, processing, and storing blood samples:[13]
   - Collect all blood samples observing standard precautions for venipuncture.
   - Allow serum samples to clot completely before centrifugation in a vertical, closure up position.
     - Nonanticoagulated tubes containing gel or a clot activator should be stored in an upright position as soon as the mixing is complete.
     - Precentrifugation serum/cells contact time is according to tube manufacturer’s recommendations. Clotting may be slowed at cooler temperatures or if patient is on anticoagulant therapy.
   - Keep tubes stoppered at all times.
   - Physically separate serum or plasma from contact with cells as soon as possible.
   - Store samples tightly stoppered at room temperature (15 to 30°C) for no longer than 24 hours.
   - If the assay will not be completed within 24 hours, refrigerate the samples at 2 to 8°C.
   - If the assay will not be completed within 6 days, or for shipment of samples beyond 6 days, freeze at -20°C or colder.
3. Use the following guidelines when preparing specimens:
   - Ensure residual fibrin and cellular matter has been removed prior to analysis.
   - Follow blood collection tube manufacturer's recommendations for centrifugation.
4. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot-to-lot.
5. Thaw samples no more than two times.
6. Avoid assaying lipemic or hemolyzed samples.

REAGENTS

PRODUCT INFORMATION

Access AMH Reagent Pack

Cat. No. B13127: 100 determinations, 2 packs, 50 tests/pack

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of 2 hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 31 days after initial use.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the reagent pack is damaged (i.e., broken elastomer), discard the pack.

R1a:	Dynabeads* paramagnetic particles coated with monoclonal anti-AMH in TRIS buffer with surfactant, protein (bovine), < 0.1% sodium azide, 0.1% ProClin** 300.
R1b:	Anti-AMH alkaline phosphatase conjugate in MES buffer, surfactant, protein (bovine, recombinant), < 0.1% sodium azide, 0.1% ProClin 300.
R1c:	TRIS buffer with surfactant, protein (murine, bovine), < 0.1% sodium azide, 0.1% ProClin 300.

*Dynabeads is a registered trademark of Dynal A.S., Oslo, Norway.

**ProClin™ is a trademark of The Dow Chemical Company (“Dow”) or an affiliated company of Dow.

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

AMH Particles (Compartment R1a)	WARNING	
		
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
AMH Conjugate (Compartment R1b)	WARNING	
		
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
AMH Sample Treatment Buffer (Compartment R1c)	WARNING	
		
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access AMH Calibrators
   Provided at zero and approximately 0.16, 0.6, 4, 10, and 24 ng/mL (1.1, 4.3, 29, 71, and 171 pmol/L).
   Cat. No. B13128
2. Access AMH QC (Quality Control) or other commercially available control material.
   Provided at approximately 1, 5 and 15 ng/mL (7.1, 36 and 107 pmol/L).
   Cat. No. B13129
3. Access Sample Diluent A
   Vial Cat. No. 81908
   Diluent Pack Cat. No. A79783 (For use with the UniCel DxI system onboard dilution feature.)
4. Access Substrate
   Cat. No. 81906
5. Access Wash Buffer II, Cat. No. A16792
   UniCel DxI Wash Buffer II, Cat. No. A16793

EQUIPMENT AND MATERIALS

R1	Access AMH Reagent Packs

CALIBRATION

CALIBRATION INFORMATION

An active calibration curve is required for all tests. For the Access AMH assay, calibration is required every 31 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

QUALITY CONTROL

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a “random access” format rather than a “batch” format, quality control materials should be included in each 24-hour time period.[14] Include Access AMH QC or other commercially available quality control materials that cover at least two levels of analyte. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

TESTING PROCEDURE(S)

PROCEDURAL COMMENTS

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.

2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use twenty (20) µL of sample for each determination in addition to the sample container and system dead volumes. Use fifty (50) µL (pickup) of sample in addition to the sample container and system dead volumes for each determination run with the DxI system onboard dilution feature (test name: dAMH). Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. The system default unit of measure for sample results is ng/mL. To change the reporting units to the International System of Units (SI Units), pmol/L (pM), refer to the appropriate system manuals and/or Help system. To manually convert concentrations to the International System, multiply ng/mL by multiplication factor 7.14.

PROCEDURE

Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

RESULTS INTERPRETATION

Patient test results are determined automatically by the system software. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration data. Patient test results can be reviewed using the appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

REPORTING RESULTS

EXPECTED RESULTS

1. Each laboratory should establish its own reference ranges to assure proper representation of specific populations.
2. In one study, AMH concentrations were measured in serum samples collected from apparently healthy adult females using the Access AMH assay on the Access 2 Immunoassay System.

Serum AMH			
Age Range (years)	**N**	**Median ng/mL (pmol/L)**	**95% Reference Interval ng/mL (pmol/L)**
18-25	120	3.6 (25.70)	1.02-14.63 (7.28-104.46)
26-30	131	3.82 (27.27)	0.69-13.39 (4.93-95.60)
31-35	120	2.47 (17.64)	0.36-10.07 (2.57-71.90)
36-40	123	1.71 (12.21)	0.18-5.68 (1.29-40.56)
41-45	126	0.54 (3.86)	0.01-2.99 (0.07-21.35)

The use of AMH in the assessment of ovarian reserve

A multi–center clinical study of 164 women was used to correlate AMH values to the antral follicle count (AFC) in women presenting to fertility clinics for evaluation. The trial enrolled women at 13 geographically diverse sites in the US who were between ≥ 21 and < 46 years of age (mean age 34.9 years, range of 23 to 45 years). The women were in their first cycle of ovarian stimulation for IVF or IVF/ICSI, with both ovaries present and a regular

menstrual cycle, and without confirmed polycystic ovary syndrome (PCOS). The mean body mass index (BMI) of all participating women averaged 25.1 with a standard deviation of ± 5.3.The AFC result was determined by transvaginal ultrasonography, which measured follicles of 2 to 10 mm in diameter. The AFC and AMH were determined on days 2-4 of the same spontaneous menstrual cycle. The trial demonstrated that the AMH levels measured for these subjects (N) correlate well with the AFC results ($r = 0.77$, $p < 0.0001$). The AFC results were sorted into 2 groups: ≤ 15 (67%) or > 15 (33%). For the > 15 AFC group the AMH cutoff is 1.77 ng/mL. The corresponding sensitivity and specificity were 88.9% and 59.1%, respectively.

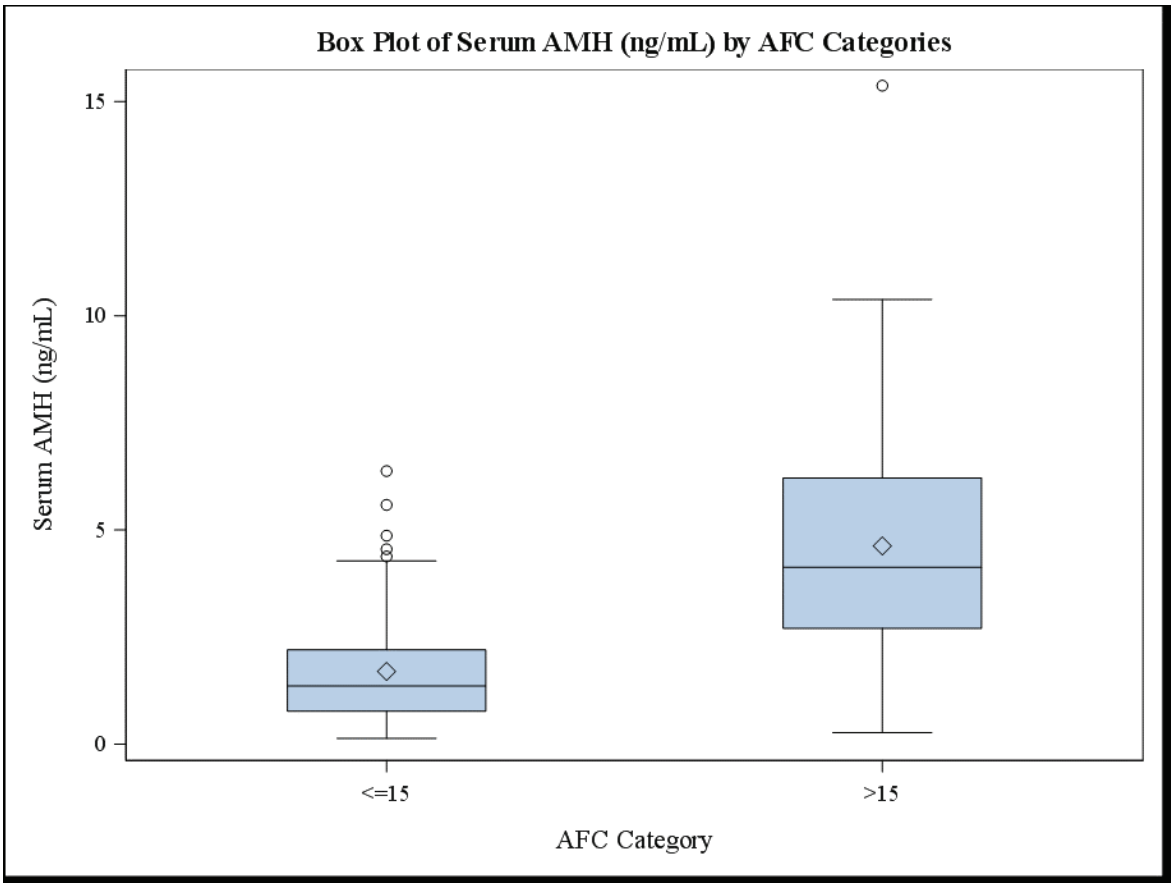
For patients with an AMH concentration that was > 1.77 ng/mL, 52% were in the > 15 AFC group and 48% were in the ≤ 15 AFC group. The study results support the system can distinguish between women with AFC values > 15 (high ovarian reserve) and women with AFC values ≤ 15 (normal or diminished ovarian reserve). The detailed findings from this clinical trial are presented in the table below.

	Total AFC		
AMH ng/mL	**≤ 15**	**> 15**	**Total**
0 to 1.77			
N	65	6	71
(%)	(91.5)	(8.5)	(43.3)
> 1.77			
N	45	48	93
(%)	(48.4)	(51.6)	(56.7)
Total			
N	110	54	164
(%)	(67.1)	(32.9)	

Based on the above study:

- For a patient with an AMH value ≤ 1.77 ng/mL, the probability to have an AFC ≤ 15 is 91.5 %, and the probability to have an AFC > 15 is 8.5 %.
- For a patient with an AMH value > 1.77 ng/mL, the probability to have an AFC > 15 is 51.6 %, and the probability to have an AFC ≤ 15 is 48.4%.

The AMH distribution is shown below by AFC category (AFC ≤ 15, > 15):



PROCEDURAL NOTES

LIMITATIONS

1. Samples can be accurately measured within the analytical range of the lower limit of quantitation and the highest calibrator value (approximately 0.08-24 ng/mL [0.57-171 pmol/L]).
   - If a sample contains less than the lower limit of quantitation for the assay, report the results as less than that value (i.e., < 0.08 ng/mL [< 0.57 pmol/L]). When the DxI system onboard dilution feature is used, the system will report results as less than 20 ng/mL (146 pmol/L).
   - If a sample contains more than the stated value of the highest Access AMH Calibrator (S5), report the result as greater than that value (i.e., > 24 ng/mL [> 171 pmol/L]). Alternatively, dilute one volume of sample with 15 volumes (1/16) of Access Sample Diluent A or dilute one volume of sample with 9 volumes (1/10) of Access Sample Diluent A. Refer to the appropriate system manuals and/or Help system for instructions on entering a sample dilution in a test request. The system reports the results adjusted for the dilution.
   - The DxI system onboard dilution feature automates the dilution process, using one volume of sample with nine volumes of Access Sample Diluent A, allowing samples to be quantitated up to approximately 240 ng/mL (1714 pmol/L). The system reports the results adjusted for the dilution.
2. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples.[15,16] Such interfering antibodies may cause erroneous results. In rare cases,

interference due to extremely high titers of antibodies to analyte-specific antibodies can occur. Carefully evaluate the applicability of this assay in patients suspected of having HAMA/heterophile antibodies.

3. 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 one or more of these products within one to two weeks of testing.
4. Other potential interferences in the patient sample could be present and may cause erroneous results in immunoassays. Some examples that have been documented in literature include rheumatoid factor, endogenous alkaline phosphatase, fibrin, and proteins capable of binding to alkaline phosphatase.[17] Carefully evaluate the results of patients suspected of having these types of interferences.
5. The Access AMH results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information. The Access AMH assay is intended to be used for assessing the ovarian reserve in conjunction with other clinical and laboratory findings before starting any fertility therapy (including pre-treatment such as GnRH agonist down-regulation therapy) and should be used in conjunction with AFC. The Access AMH assay is not intended to be used for monitoring of women undergoing controlled ovarian stimulation in an Assisted Reproduction Technology program.
6. The Access AMH assay does not demonstrate any “hook” effect up to 1,000 ng/mL.
7. Samples for AMH levels should be drawn on days 2-4 of the menstrual cycle.

PERFORMANCE CHARACTERISTICS

METHODS COMPARISON

Representative data for methods comparison are provided for illustration only. Performance obtained in individual laboratories may vary.

This method comparison study was conducted using a protocol based on CLSI EP09-A3.[18] 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:

n	Range of Observations (ng/mL)	Intercept (ng/mL)	Slope (95% CI)	Correlation Coefficient (r)
121	0.070 to 22.80	0.04	1.03 (1.01 - 1.06)	0.99

Linearity

Representative data for linearity are provided for illustration only. Performance obtained in individual laboratories may vary.

Based on CLSI EP06-A[19] one high sample (>24 ng/mL) and one low sample (<0.02 ng/mL) were mixed to make 7 evenly distributed sample concentrations. Four replicates of the 7 mixed samples, 8 replicates of the low sample and 4 replicates of the high sample were run on a single Access 2 instrument. The Access AMH assay was designed to be linear, with a maximum deviation from linearity of ≤ 5.0% for samples > 0.16 ng/mL, and ≤ 0.04 ng/mL for samples ≤ 0.16 ng/mL. One study, analyzed using a polynomial regression method demonstrated a maximum deviation from linearity of 4.8% for samples > 0.16 ng/mL and < 0.00 ng/mL for samples ≤ 0.16 ng/mL.

Imprecision

Representative data for imprecision are provided for illustration only. Performance obtained in individual laboratories may vary.

The Access AMH assay exhibits total imprecision ≤ 10.0% at concentrations ≥ 0.16 ng/mL, and total standard deviation (SD) ≤ 0.032 ng/mL, at concentrations < 0.16 ng/mL. One study, using human serum samples involved a total of 40 assays with 2 replicates per assay, over 20 days. The following data were calculated based on CLSI EP05-A3[20] guidelines.

	AMH (ng/mL) n=240	Within-Run		Between-Run		Intra-study (Within Lab)		Inter-study		Total Imprecision	
	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	0.09	0.002	2.8	0.001	1.7	0.003	3.3	0.004	4.4	0.005	5.5
Sample 2	2.61	0.052	2.0	0.041	1.6	0.066	2.5	0.035	1.3	0.075	2.9
Sample 3	8.56	0.161	1.9	0.175	2.0	0.238	2.8	0.152	1.8	0.282	3.3
Sample 4	17.16	0.380	2.2	0.289	1.7	0.478	2.8	0.155	0.9	0.502	2.9

Reproducibility was evaluated at four sites. Six samples spanning the analytical measuring range and three quality control samples were tested. Samples were evaluated on four Access 2 instruments in four replicates with two runs per day for 10 days. The following data were calculated based on CLSI EP05-A3[20] guidelines.

	AMH (ng/mL) N=320	Within Run (Repeatability)		Within Day		Between Day		Between Site		Reproducibility (Total Imprecision)	
	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	0.48	0.010	2.1	0.003	0.6	0*	N/A	0.010	2.1	0.015	3.1
Sample 2	0.94	0.017	2.1	0.001	0.1	0.005	0.5	0.024	2.5	0.030	3.2
Sample 3	2.58	0.049	1.9	0.010	0.4	0.018	0.7	0.055	2.1	0.076	2.9
Sample 4	5.14	0.100	1.9	0.050	1.0	0*	N/A	0.094	1.8	0.146	2.8
Sample 5	10.21	0.182	1.8	0.060	0.6	0.051	0.5	0.158	1.5	0.253	2.5
Sample 6	16.16	0.292	1.8	0.107	0.7	0*	N/A	0.181	1.1	0.360	2.2
QC1	1.00	0.023	2.0	0.002	0.2	0.004	0.4	0.021	2.1	0.032	3.2
QC2	5.04	0.106	2.2	0.015	0.3	0.035	0.7	0.086	1.7	0.141	2.8
QC3	15.22	0.345	2.3	0.054	0.4	0.051	0.3	0.006	0.0	0.353	2.3

*Default value when estimated variance was negative.

Analytical Specificity / Interferences

Representative data for analytical specificity/interferences are provided for illustration only. Performance obtained in individual laboratories may vary.

Serum samples with AMH concentrations of approximately 2 and 10 ng/mL (14.3 and 71 pmol/L) were spiked with concentrations of the substances below and run on a single Access 2 Immunoassay System. Total protein (human serum albumin) was tested in serum samples with AMH concentrations of approximately 2 and 7 ng/mL (14.3 and 50 pmol/L). Values were calculated as described in CLSI EP07-A2.[21] Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). There was no significant interference (exceeding 10% shift in dose) observed when the following substances were tested at the indicated concentrations. HAMA/heterophile has not been evaluated as an interferent.

Substance	Highest Concentration Added
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	65 mg/dL
Ampicillin sodium salt	1000 mg/L
Ascorbic Acid	170 µmol/L
Bilirubin (conjugated)	43 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Biotin	179 ng/mL
Cefoxitin sodium salt	2500 mg/L
Cyclosporin A	5 mg/L
doxycycline hyclate	50 mg/L
Folic acid	0.4 mg/L
Gamma Globulin	60 mg/mL
Hemoglobin	1 g/dL
Heparin (low molecular weight)	3000 U/L
Ibuprofen	50 mg/dL
IgA	1.8 g/dL
IgG	2.5 g/dL
IgM	0.5 g/dL
Intralipids	37 mmol/L
Levodopa	20 mg/L
Levothyroxine sodium hydrate	0.2 mg/L
Metformin	2000 mg/L
Methyldopa	20 mg/L
Metronidazole	200 mg/L
N-Acetyl-L-cysteine	150 mg/L
Phenylbutazone	400 mg/L
Rheumatoid Factor	1000 IU/mL
Rifampicin	60 mg/L
Theophylline	100 mg/L
Triptoréline (Gonapeptyl)	0.1 mg/L
Total protein (human serum albumin)	12 g/dL
Uric Acid	1.4 mmol/L

Cross reactivity was tested in serum samples with AMH concentrations of approximately 2 and 10 ng/mL (14.3 and 71 pmol/L) spiked with concentrations of the substances below and run on a single Access 2 Immunoassay System. Activin A was tested in serum samples with AMH concentrations of approximately 1 and 5 ng/mL (7.1 and 36 pmol/L). Values were calculated as described in CLSI EP07-A2.[21] There was no significant cross reactivity (exceeding 5% cross reactivity) observed when the following substances were tested at the indicated concentrations.

Substance	Highest Concentration Added
Inhibin A	100 ng/mL
Activin A	16.32 µg/mL
hLH	100 mIU/mL
hFSH	115 mIU/mL
TGF β-1	65 ng/mL

Limit of Blank

Representative data for Limit of Blank is provided for illustration only. Performance obtained in individual laboratories may vary.

The Access AMH assay is designed to have a Limit of Blank (LoB) of ≤ 0.01 ng/mL (0.07 pmol/L). In one study, LoB was tested using a protocol based on CLSI EP17-A2.[22] A total of 240 replicates of a zero analyte sample, the Access AMH S0 calibrator, were measured in 12 runs using multiple reagent packs and calibrator lots on multiple Access 2 Systems. This study determined the LoB for Access AMH to be 0.0040 ng/mL (0.029 pmol/L).

Limit of Detection

Representative data for Limit of Detection is provided for illustration only. Performance obtained in individual laboratories may vary.

The Access AMH assay was designed to have a Limit of Detection (LoD) of ≤ 0.02 ng/mL (0.14 pmol/L). In one study, LoD was tested using a protocol based on CLSI EP17-A2.[22] Nine replicates each from seven low-level samples were measured using multiple reagent pack lots and one calibrator lot in ten runs on multiple Access 2 Systems. This study determined the LoD for Access AMH to be 0.0098 ng/mL (0.07 pmol/L).

Limit of Quantitation

Representative data for Limit of Quantitation is provided for illustration only. Performance obtained in individual laboratories may vary.

The Access AMH assay was designed to have a Limit of Quantitation (LoQ) of ≤ 0.08 ng/mL (0.57 pmol/L). In one study, LoQ was tested using a protocol based on CLSI EP17-A2.[22] Nine replicates of seven low-level samples were measured using multiple reagent pack lots and one calibrator lot in ten runs on multiple Access 2 Systems. This study determined the LoQ for Access AMH to be 0.013 ng/mL (0.093 pmol/L).

ADDITIONAL INFORMATION

SYMBOLS KEY

Glossary of Symbols is available at techdocs.beckmancoulter.com (document number C02724)

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