

Instructions For Use

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Access AMH Calibrators Anti-müllerian hormone (AMH) calibrators

REF B13128

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The Access AMH Calibrators are intended to calibrate the Access AMH assay for the quantitative determination of anti-Müllerian hormone (AMH) levels in human serum and plasma using the Access Immunoassay Systems as an aid in the assessment of ovarian reserve.

SUMMARY AND EXPLANATION

Quantitative assay calibration is the process by which samples with known analyte concentrations (i.e., assay calibrators) are tested like patient samples to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. This mathematical relationship, or calibration curve, is used to convert RLU (Relative Light Unit) measurements of patient samples to specific quantitative analyte concentrations.

TRACEABILITY

The measurand (analyte) in the Access AMH Calibrators is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the Access reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

REAGENTS

PRODUCT INFORMATION

Access AMH Calibrators

Cat. No. B13128: S0–S5, 2 mL/vial

- Provided lyophilized.
- Reconstitute each vial volumetrically with 2 mL distilled water. Allow 30 minutes for dissolution. Mix gently before use.

- Lyophilized calibrators are stable until the expiration date stated on the label when stored at 2 to 10°C.
- Reconstituted stability is 90 days at 2-10°C.
- Signs of possible deterioration are control values out of range or failure of calibrators to completely reconstitute.
- Refer to calibration card for exact concentrations.

S0:	HEPES BSA buffer with 0.5% ProClin* 300 and preservative. Contains 0 ng/mL (0 pmol/L) AMH.
S1, S2, S3, S4, S5:	Recombinant human AMH at levels of approximately 0.16, 0.6, 4, 10 and 24 ng/mL (1.1, 4.3, 29, 71, and 171 pmol/L), respectively in, HEPES BSA buffer with 0.5% ProClin 300 and preservative.
Calibration Card:	1

*ProClin is a trademark of Rohm and Haas Company or of its subsidiaries or affiliates.

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.
- Xi. Irritant: 0.5% ProClin 300
R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.
- The Material Safety Data Sheet (MSDS) is available upon request.

CALIBRATION

CALIBRATION INFORMATION

The Access AMH Calibrators are provided at 6 levels – zero and approximately 0.16, 0.6, 4, 10 and 24 ng/mL (1.1, 4.3, 29, 71, and 171 pmol/L). Assay calibration data are valid up to 31 days.

Run the Access AMH Calibrator S0 in quadruplicate, and the Calibrator S1–S5 in duplicate.

TESTING PROCEDURE(S)

Procedure

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.


PROCEDURAL NOTES

LIMITATIONS

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

ADDITIONAL INFORMATION

Beckman Coulter and Access are trademarks of Beckman Coulter, Inc.; Beckman Coulter and Access are registered in the USPTO and SIPO.

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