BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

Access AMH QC
Anti-Müllerian hormone (AMH) QC

REF B13129

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The Access AMH QC is intended for monitoring system performance of the Access AMH assay.

SUMMARY AND EXPLANATION

Quality control (QC) materials simulate the characteristics of patient samples and are essential for monitoring the system performance of the Access AMH immunoassay. In addition, they are an integral part of good laboratory practices.[1,2,3,4,5,6] When performing assays with Access reagents for AMH, include quality control materials to validate the integrity of the assays. The assayed values should fall within the acceptable range if the test system is working properly.

TRACEABILITY

The measurand (analyte) in the Access AMH QC 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 QC 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 QC

Cat. No. B13129: 2 mL/vial, 2 vials/each level

- Provided lyophilized.
- Reconstitute each vial volumetrically with 2 mL distilled water. Allow 30 minutes for dissolution. Mix gently before use.
- Lyophilized controls are stable until the expiration date stated on the label when stored at 2 to 10°C.
- Reconstituted vial is stable at 2 to 10°C for 2 days after initial use or for 60 days when stored frozen at -15 to -30°C.

- Thaw no more than 3 times.
- Signs of possible deterioration are control values out of range or controls do not completely reconstitute.
- Refer to the QC value card for mean values and standard deviations (SD).

QC1:	Recombinant human AMH at approximately 1 ng/mL (7.1 pmol/L), processed human plasma matrix, 0.5% ProClin* 300.
QC2:	Recombinant human AMH at approximately 5 ng/mL (36 pmol/L), processed human plasma matrix, 0.5% ProClin 300.
QC3:	Recombinant human AMH at approximately 15 ng/mL, (107 pmol/L) processed human plasma matrix, 0.5% ProClin 300.
QC Value 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.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[7]
- 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.

TESTING PROCEDURE(S)

Procedure

Determine the concentration of AMH in the Access AMH QC materials using the Access Immunoassay System in the same manner as a patient sample. 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.[1] 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. Refer to the appropriate system manuals and/or Help system for information on quality control theory, configuring controls, quality control sample test request entry, and reviewing quality control data.

REPORTING RESULTS

EXPECTED RESULTS

For the value assignment of the Access AMH QC material, a number of samples, representative of the entire lot, are selected and assayed to provide a reliable estimate of the mean value. The mean values and standard deviations are

listed on the QC value card. Variations, such as in technique, equipment, or reagents may result in values different from those listed. Therefore, each laboratory should establish its own mean values and standard deviations (SD).

PROCEDURAL NOTES

LIMITATIONS

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

ADDITIONAL INFORMATION

REFERENCES

1. Cembrowski GS, Carey RN. Laboratory quality management: QC ≒ QA. ASCP Press, Chicago, IL, 1989.
2. Boome HE, Cembrowski GS, Kahn SN, Martin PL, Patrick CA. 1985. Implementation and use of a manual multi-rule quality control procedure. Lab Med; 16: 533-537.
3. Westgard JO, Barry PL, Hunt MR, Groth T. 1981. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem 27: 493-501.
4. Koch DD, Oryall JJ, Quam EF, Feldbruegger DH, et al. Selection of medically useful QC procedures for individual tests done in a multitest analytical system. Clin Chem 1990; 36: 230-233.
5. Mugan K, Carlson IH, Westgard JO. 1994. Planning QC procedures for immunoassays. J Clin Immunoassay 17: 216-222.
6. Approved Guideline - Statistical Quality Control for Quantitative Measurements: Principles and Definitions, C24-A3. June 2006. Clinical and Laboratory Standards Institute.
7. HHS Publication, 5th ed., December 2009. Biosafety in Microbiological and Biomedical Laboratories.

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