Linearity LQ Ammonia/Alcohol for Ortho Vitros

REF K830M-5

5 x 2 mL

LOT 07141

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

IVD

2027-04-01

ENGLISH

INTENDED USE

The Audit® MicroControls™ Linearity LQ Ammonia/Alcohol for Ortho Vitros is intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for the following analyte: Ammonia and Alcohol.

The Audit® MicroControls™ Linearity LQ Ammonia/Alcohol for Ortho Vitros is for In Vitro Diagnostic use only.

SUMMARY AND PRINCIPLE

As defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control (CDC), each laboratory must revalidate each test method's AMR at least every six months as well as following changes in lots of analytically critical reagents or major system components[2]. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Linearity LQ Ammonia/Alcohol for Ortho Vitros may be used as one would use human blood to verify and validate the AMR.

WARNINGS AND PRECAUTIONS

Linearity LQ Ammonia/Alcohol for Ortho Vitros is intended solely for the purpose of in vitro diagnostic use as described on the label. AUDIT® MicroControls™, Inc. will not be liable for any unclaimed damages arising from any other usage.

MATERIALS PROVIDED

The Linearity LQ Ammonia/Alcohol for Ortho Vitros is an IVD device consisting of 5 levels of liquid material and additives in buffer solution.

Linearity LQ Ammonia/Alcohol for Ortho Vitros, 5 x 2 mL

STORAGE AND STABILITY

Linearity LQ Ammonia/Alcohol for Ortho Vitros is stored at 2-8C and will remain stable in the unopened bottle until the expiration date. Do not store in a frost-free freezer. After opening, the contents should be used according to the instrument manufacturer's instructions and stored at 2-8C for 2 days.

PROCEDURE

Follow the manufacturer's instructions provided for quality control and for verifying and validating the AMR. Verify that the lot number on each bottle matches the package insert. To avoid evaporation, do not leave the bottle uncapped. Q.C. requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Calibration verification linearity material should be run[3]:

1. every six (6) months.
2. when a complete change of reagents for a procedure is introduced.
3. when there is major preventive maintenance or replacement of critical parts that may influence test performance.
4. when control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits.
5. when the laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

INSTRUCTIONS FOR USE

1. Remove a vial from the package and mix by gentle inversion. Do not shake. Do not mix mechanically.
2. Use immediately or return to 2-8°C.
3. The vial should remain stored at 2-8°C at all times. If additional sampling is necessary, the time outisde of 2-8°C storage should be minimized.

CALCULATIONS OF RESULTS

Each set of Linearity LQ Ammonia/Alcohol for Ortho Vitros is prepared in a manner such that an equal distance exists between each consecutive level. This dilution scheme is consistent with the CLSI recommendation[1] for preparing linearity sets.

U.S. customers only - Once each bottle of the total set is tested, raw data may be entered via the AUDITOR™ QC Program at www.auditmicro.com. An on-line graph showing actual values versus predicted values for each analyte is then available to print, along with slope and intercept data. Call (866) 25-AUDIT for more information.

LIMITATIONS OF THE PROCEDURE

If the contents of any of the vials become frozen, discard all vials and request a replacement set, as the results will not be valid.

This product is intended for use with quantitative assays on the indicated analyzer provided in this package insert.

The Linearity LQ Ammonia/Alcohol for Ortho Vitros should not be used for calibration or standardization of Ammonia and Alcohol assays.

Target values and ranges are intended only as guidelines. Laboratories should determine ranges based on their own test system and tolerance limit.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

EXPECTED VALUES

Each lot of product is manufactured such that a linear relationship exists among levels. Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument/reagent system calibration. The degree of acceptable non-linearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte. The material and information presented here in no manner constitutes an overruling of any federal, state or other regulatory body's regulations and/or guidelines.

ORDERING INFORMATION

PRODUCT NUMBER	PRODUCT DESCRIPTION	PRODUCT PACKAGING
K830M-5	Linearity LQ Ammonia/Alcohol for Ortho Vitros	5 x 2 mL

Distributed by AUDIT® MicroControls™, Inc. - U.S. customers only please call (866) 252-8348 or www.auditmicro.com

[1] Dilution schemes are based on guidelines provided by The Clinical and Laboratory Standard Institute (CLSI) in approved guideline EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline", April 2003.

[2] Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; p.3690.

[3] Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1255, (b) (1) (ii).

	Instrument	Units	A	B	C	D	E
Ammonia	Ortho Vitros	umol/L	16.2	121	233	340	441
Alcohol	Ortho Vitros	mg/dL	20.3	87.5	147	207	257

REF Catalog Number

IVD For In Vitro Diagnostic Use

Use By (YYYY-MM-DD)

LOT Lot Number

Caution

www.auditmicro.com/inserts

2 – 8°C Temperature Limit

Manufactured By

INS302 REV: New
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