Linearity LQ Ammonia/Ethanol for Roche Systems

REF **K881M-5**

5 x 2 mL

LOT 07110

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

IVD

2026-12-30

INTENDED USE

The Linearity LQ Ammonia/Ethanol for Roche Systems is a five level linearity set. Each level contains the following analytes: Ammonia and Ethanol. These five levels demonstrate a linear relationship to each other for their respective analytes[1]. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Ammonia and Ethanol.

This product is intended for use on Roche Clinical Chemistry Analyzers. The Linearity LQ Ammonia/Ethanol for Roche Systems should not be used for calibration or standardization of the Ammonia and Ethanol assays. The Linearity LQ Ammonia/Ethanol for Roche Systems 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/Ethanol for Roche Systems may be used as one would use human serum to verify and validate the AMR.

WARNINGS AND PRECAUTIONS

Linearity LQ Ammonia/Ethanol for Roche Systems 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

Linearity LQ Ammonia/Ethanol for Roche Systems, 5 x 2 mL

STORAGE AND STABILITY

Linearity LQ Ammonia/Ethanol for Roche Systems is stored at 2-8°C and will remain stable in the unopened vial until the expiration date. After opening, the contents should be used according to the instrument manufacturer's instructions and immediately returned to 2-8°C.

When used to monitor the precision of laboratory testing procedures for its assays, Linearity LQ Ammonia/Ethanol for Roche Systems has an open vial stability of up to 48 hours under the proper storage conditions. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial stability claim. Make sure the contents of the vial are well mixed before use.

PROCEDURE

Follow the manufacturer's instructions provided for quality control and for verifying and validating the AMR. Verify that the lot number on each vial matches the package insert. To avoid evaporation, do not leave the vial 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/Ethanol for Roche Systems 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 vial 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.

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
K881M-5	Linearity LQ Ammonia/Ethanol for Roche Systems	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).

	Units	Instrument	A	B	C	D	E
Ammonia	µmol/L	Roche, Cobas c501	23	228	435	637	841
Ethanol	mg/dL	Roche, Cobas c501	15.5	129	236	356	462

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

INS163 REV: 009
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