

Linearity FLQ TDM for Roche Systems

REF

K933M-5

5 x 4 mL

LOT

07146

2027-08-22

Aalto Scientific Ltd
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Eatonton, GA 31024
USA



ENGLISH

INTENDED USE

The Audit[®] MicroControls[™] Linearity FLQ TDM for Roche Systems is intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for the following analytes: Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, NAPA, Phenobarbital, Phenytoin, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid, Vancomycin.

The Audit[®] MicroControls[™] Linearity FLQ TDM 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 components². Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Linearity FLQ TDM for Roche Systems may be used as one would use human blood to verify and validate the AMR.

WARNINGS AND PRECAUTIONS

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

MATERIALS PROVIDED

The Linearity FLQ TDM for Roche Systems is an IVD device consisting of 5 levels of liquid material and additives in human serum.

Linearity FLQ TDM for Roche Systems, 5 x 4 mL.

STORAGE AND STABILITY

Linearity FLQ TDM for Roche Systems may arrive thawed. It should be stored at -15°C or colder upon receipt until use.

Linearity FLQ TDM for Roche Systems is stored at -15°C or colder and will remain stable in the unopened bottle until the expiration date. Do not store in a frost-free freezer. After thawing, the contents should be used according to the instrument manufacturer's instructions and stored at 2-8°C for 5 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 run³:

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

INSTRUCTIONS FOR USE

- Remove the bottles from the freezer and allow to thaw at room temperature. Do not shake. Do not mix mechanically.
- Mix gently by inversion to assure complete mixing of the contents.
- Remove cap and invert bottle. Gently squeeze the dropper bottle.
- After sampling, wipe off dropper tip, replace cap, and store at 2-8°C.

CALCULATIONS OF RESULTS

Each set of Linearity FLQ TDM 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 recommendation¹ 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

The Linearity FLQ TDM for Roche Systems should not be used for calibration or standardization of the Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, NAPA, Phenobarbital, Phenytoin, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid, Vancomycin assay.

Values reported are typical values and are intended only as guidelines.

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
K933M-5	Linearity FLQ TDM for Roche Systems	5 x 4 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).

Roche Cobas						
	Units	A	B	C	D	E
Acetaminophen	µg/mL	10.4	53.9	98.1	140	180
Amikacin	µg/mL	1.5	10.4	19.1	26.9	34.7
Carbamazepine	µg/mL	2.35	6.10	9.81	13.8	17.5
Digoxin	ng/mL	0.37	1.48	2.53	3.69	4.65
Gentamicin	µg/mL	1.0	3.3	5.1	7.0	8.8
Lithium	mmol/L	0.216	0.855	1.50	2.14	2.76
Phenobarbital	µg/mL	3.4	14.2	25.6	37.9	48.2
Phenytoin	µg/mL	1.6	11.0	19.8	28.8	37.7
Procainamide	µg/mL	0.74	3.18	5.74	8.08	11.1
Quinidine	µg/mL	0.55	2.19	3.94	5.56	6.90
Salicylate	mg/dL	0.96	16.1	32.0	48.3	62.8
Theophylline	µg/mL	1.4	9.9	18.3	26.7	34.4
Tobramycin	µg/mL	0.66	2.53	4.63	6.85	8.72
Valproic Acid	µg/mL	8.0	40.1	73.4	112	141
Vancomycin	µg/mL	6.1	21.0	36.2	53.6	70.0