Linearity FD Urine/Fluids Chemistry

REF **K723M-5**
10 x 3 mL

LOT 07145A, 07145B, 07145C, 07145D, 07145E
07145AA, 07145BB, 07145CC, 07145DD, 07145EE

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IVD

2027-07-22

ENGLISH

INTENDED USE

The Linearity FD Urine/Fluids Chemistry is assayed quality control material consisting of two sets of five levels of aqueous buffer. Each level of the Linearity FD Urine/Fluids Chemistry Set 1 contains the following analytes: Osmolality, Phosphorous, Urea Nitrogen, Uric Acid. Each level of the Linearity FD Urine/Fluids Chemistry Set 2 contains the following analytes: Amylase, Calcium, Chloride, Creatinine, Glucose, Magnesium, Microalbumin, Protein, Potassium, Sodium. These five levels of each set demonstrate a linear relationship to each other for their respective analytes[1]. It is intended to simulate human patient urine/fluids samples for purpose of determining linearity, calibration verification and verification of reportable range for Osmolality, Phosphorous, Urea Nitrogen, Uric Acid and Amylase, Calcium, Chloride, Creatinine, Glucose, Magnesium, Microalbumin, Protein, Potassium, Sodium.

This product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Linearity FD Urine/Fluids Chemistry should not be used for calibration or standardization of the Osmolality, Phosphorous, Urea Nitrogen, Uric Acid, and Amylase, Calcium, Chloride, Creatinine, Glucose, Magnesium, Microalbumin, Protein, Potassium, Sodium assays. The Linearity FD Urine/Fluids Chemistry 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 FD Urine/Fluids Chemistry may be used as one would use human urine/fluids 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.

This product contains less than 0.1% sodium azide that may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Linearity FD Urine/Fluids Chemistry 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 FD Urine/Fluids Chemistry Set 1, 5 x 3 mL
Linearity FD Urine/Fluids Chemistry Set 2, 5 x 3 mL

STORAGE AND STABILITY

Linearity FD Urine/Fluids Chemistry 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 FD Urine/Fluids Chemistry Set 1 has a reconstituted stability of up to 6 days and Set 2 has a reconstituted stability of up to 10 days 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.
2. Using a pipette, reconstitute the product with 3 mL of deionized water.
3. Allow the vial to sit at room temperature for 5 minutes.
4. Occasionally swirl for 15 minutes, or until all visible material is dissolved. Do not shake. Do not mix mechanically. Avoid getting any undissolved material on the sides of the vial or the stopper.
5. When all visible solid material is dissolved, invert several times to dissolve any material on the stopper.
6. Swirl occasionally for at least 5 minutes.
7. Use immediately or return to 2-8°C.
8. The vial should remain stored at 2-8°C at all times. If additional sampling is necessary, the time outside of 2-8°C storage should be minimized.

CALCULATIONS OF RESULTS

Each set of Linearity FD Urine/Fluids Chemistry 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 all levels. The analyte concentrations in this insert were derived from multiple replicate analyses. 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
K723M-5	Linearity FD Urine/Fluids Chemistry	10 x 3 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)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).

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
3.0 mL DI H_2O Reconstitute With

2025-09-30
INS154 REV: 011

Linearity FD Urine/Fluids Chemistry Set 1							
	Units	Instrument / Reagent	A	B	C	D	E
Phosphorous	mg/dL	*Cobas c501, Roche*	9.1	70.3	125	181	230
Urea Nitrogen	mg/dL	*Cobas c501, Roche*	21.8	906	1739	2505	3242
Uric Acid	mg/dL	*Cobas c501, Roche*	8.4	32.3	54.5	74.4	95.0
Osmolality	mmol/kg	*Cobas c501, Roche*	27	430	806	1175	1534

Linearity FD Urine/Fluids Chemistry Set 2							
	Units	Instrument / Reagent	A	B	C	D	E
Amylase	IU/L	*Cobas c501, Roche*	10	369	713	1070	1373
Calcium	mg/dL	*Cobas c501, Roche*	1.4	11.4	21.2	>30	>30
Chloride	mEq/L	*Cobas c501, Roche*	<20	58.3	108	161	209
Creatinine	mg/dL	*Cobas c501, Roche*	11.8	158	304	449	579
Glucose	mg/dL	*Cobas c501, Roche*	12	179	338	515	659
Magnesium	mg/dL	*Cobas c501, Roche*	2.75	7.39	11.9	16.8	20.9
Microalbumin	mg/dL	*Cobas c501, Roche*	2	10	18	27	35
Potassium	mEq/L	*Cobas c501, Roche*	4.88	24.5	44.1	63.7	80.4
Protein	mg/dL	*Cobas c501, Roche*	8.4	47.1	86.4	131	170
Sodium	mEq/L	*Cobas c501, Roche*	22	67	112	161	204