Linearity FD General Chemistry Beckman AU

REF **K824M-5**

10 x 3 mL

LOT 07155A, 07155B, 07155C, 07155D, 07155E

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

IVD

2028-07-23

INTENDED USE

The Linearity FD General Chemistry Beckman AU is assayed quality control material consisting of five levels of human serum. Each level of the Linearity FD General Chemistry Beckman AU contains the following analytes: Albumin, Alkaline Phosphatase, ALT, Amylase, AST, BUN, Calcium, Chloride, CO2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, Iron, Lactate, LDH, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, and Uric Acid. 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 Albumin, Alkaline Phosphatase, ALT, Amylase, AST, BUN, Calcium, Chloride, CO2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, Iron, Lactate, LDH, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, and Uric Acid.

This product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Linearity FD General Chemistry Beckman AU should not be used for calibration or standardization of the Albumin, Alkaline Phosphatase, ALT, Amylase, AST, BUN, Calcium, Chloride, CO2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, Iron, Lactate, LDH, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, and Uric Acid assays. The Linearity FD General Chemistry Beckman AU 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 General Chemistry Beckman AU may be used as one would use human whole 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.

Linearity FD General Chemistry Beckman AU 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 General Chemistry Beckman AU, 5 x 3 mL

Linearity FD General Chemistry Beckman AU Diluent, 5 x 3 mL

STORAGE AND STABILITY

Linearity FD General Chemistry Beckman AU 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 General Chemistry Beckman AU has a reconstituted stability of up to 7 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, measure out 3 mL of the provided matched diluent and reconstitute the product. Do not pour contents of matched diluent into the product as there may be more than 3 mL of matched diluent provided.
3. Allow the vial to sit at room temperature for 5 minutes.
4. Occasionally swirl for 45 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

Linearity FD General Chemistry Beckman AU 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
K824M-5	Linearity FD General Chemistry Beckman AU	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 Diluent — Reconstitute With

INS170 REV: 008
2025-09-29

	Units	Instrument	A	B	C	D	E
Albumin	g/dL	Beckman AU 480	2.8	4.0	5.1	>6.0	>6.0
Alkaline Phosphatase	U/L	Beckman AU 480	11	418	788	1131	*1489
ALT (GPT)	U/L	Beckman AU 480	12	137	257	366	476
Amylase	U/L	Beckman AU 480	16	544	1020	1459	*1914
AST (GOT)	U/L	Beckman AU 480	12	261	491	701	901
BUN	mg/dL	Beckman AU 480	6	42	75	104	>130
Calcium	mg/dL	Beckman AU 480	4.6	8.0	11.0	14.0	*16.7
Chloride	mEq/L	Beckman AU 480	59	92	124	154	184
CO2	mEq/L	Beckman AU 480	4	13	23	35	*39
Creatine Kinase (CK)	U/L	Beckman AU 480	18	570	1005	1474	1889
Creatinine	mg/dL	Beckman AU 480	0.35	7.37	13.7	19.3	>25.0
Gamma-GT (GGT)	U/L	Beckman AU 480	12	317	594	849	1089
Glucose	mg/dL	Beckman AU 480	22	226	417	597	768
Iron	µg/dL	Beckman AU 480	63.3	302	535	753	972
Lactate	mg/dL	Beckman AU 480	4.2	27.6	49.5	70.8	>90.0
Lactate Dehydrogenase (LDH)	U/L	Beckman AU 480	35	358	650	914	>1200
Lipase	U/L	Beckman AU 480	10	177	303	412	509
Magnesium	mg/dL	Beckman AU 480	0.7	2.5	4.2	5.8	*7.3
Phosphorous	mg/dL	Beckman AU 480	1.1	5.7	10.1	14.2	18.4
Potassium	mEq/L	Beckman AU 480	1.5	3.7	5.9	7.9	*9.7
Sodium	mEq/L	Beckman AU 480	62	92	122	148	174
Total Protein	g/dL	Beckman AU 480	3.2	5.2	7.1	8.8	10.4
Uric Acid	mg/dL	Beckman AU 480	1.7	9.2	16.2	22.5	28.4

* Values obtained by dilution

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2025-09-29