



Linearity FD Immunoassay for Abbott Systems

REFK833M-5

5 x 5 mL

LOT07204



Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA



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INTENDED USE

The Audit MicroControls™ Linearity FD Immunoassay for Abbott Systems is intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range on automated clinical instruments for the following analyte(s): AFP, CEA, Cortisol, DHEA, Estradiol, Ferritin, Folate, Free PSA, FSH, HCG, LH, Progesterone, Prolactin, Testosterone, Total PSA, TSH, and Vitamin B12.

The Audit MicroControls™ Linearity FD Immunoassay for Abbott 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 FD Immunoassay for Abbott Systems may be used as one would use human patient sample 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 Immunoassay for Abbott 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

The Linearity FD Immunoassay for Abbott Systems is an IVD device consisting of 5 levels of freeze dried material and additives in human serum and bovine serum albumin.

Linearity FD Immunoassay for Abbott Systems, 5 x 5 mL

STORAGE AND STABILITY

Linearity FD Immunoassay for Abbott Systems is stored at 2-8°C and will remain stable in the unopened vial until the expiration date. After reconstituting, 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 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 run³:

- 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

For laboratory professional use only.

- 1. Remove a vial from the package.
- 2. Using a pipette, reconstitute the product with 5 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 Immunoassay for Abbott 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.

Additional intermediate levels may be obtained by preparing a mixture of the provided levels. For assistance in preparing and evaluating such additional intermediate levels, please contact technical service by calling (866) 25-AUDIT or emailing technicalsupport@auditmicro.com.

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

The Linearity FD Immunoassay for Abbott Systems should not be used for calibration or standardization of AFP, CEA, Cortisol, DHEA, Estradiol, Ferritin, Folate, Free PSA, FSH, HCG, LH, Progesterone, Prolactin, Testosterone, Total PSA, TSH, and Vitamin B12 assays.

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

TARGET VALUES

The target values provided are intended for guidance only. Each laboratory should establish their own acceptable ranges according to internal laboratory procedures.

TYPICAL 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
K833M-5	Linearity FD Immunoassay for Abbott Systems	5 x 5 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.
² Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline", April 2003.
³ 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).



Catalog Number



In Vitro Diagnostic Medical Device



Use By (YYYY_MM_DD)



Lot Number



Caution



Biological Risks



www.auditmicro.com/inserts
Consult Instructions For Use



Temperature Limit



Manufactured By



Reconstitute With

5 mL DI H₂O

Analyte	Reagent, Instrument	Units	A	B	C	D	E
AFP	Abbott, Alinity I	ng/mL	2.82	444	907	1435	1837
CEA	Abbott, Alinity I	ng/mL	2.06	286	601	908	1218
Cortisol	Abbott, Alinity I	µg/dL	1.6	15.5	29.3	44.1	>59.8
DHEA	Abbott, Alinity I	µg/dL	6.9	343	670	1002	1350
Estradiol	Abbott, Alinity I	pg/mL	37	280	551	832	>1000
Ferritin	Abbott, Alinity I	ng/mL	2.27	291	556	834	1347
Folate	Abbott, Alinity I	ng/mL	2.6	6.1	10.4	15.3	19.7
Free PSA	Abbott, Alinity I	ng/mL	0.288	7.22	14.4	21.5	28.8
FSH	Abbott, Alinity I	mIU/mL	0.19	30.6	60.2	91.1	124
HCG	Abbott, Alinity I	mIU/mL	5.32	3213	6599	10,351	14,346
LH	Abbott, Alinity I	mIU/mL	0.24	53.8	108	163	217
Progesterone	Abbott, Alinity I	ng/mL	0.6	10.2	20.2	29.5	39.3
Prolactin	Abbott, Alinity I	ng/mL	1.21	39.2	78.1	120	166
Testosterone	Abbott, Alinity I	ng/dL	10.6*	423	810	1206	>1500
Total PSA	Abbott, Alinity I	ng/mL	0.320	23.8	46.1	65.6	84.2
TSH	Abbott, Alinity I	µIU/mL	0.017	22.0	44.6	67.4	94.2
Vitamin B12	Abbott, Alinity I	pg/mL	176	573	1010	1457	1751

* Testosterone ran with autodilution turned off.