



Linearity LQ Direct TIBC for Ortho Vitros

REFK905M-5

5 x 2 mL

LOT07208



Aalto Scientific Ltd
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Eatonton, GA 31024
USA



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INTENDED USE

The Audit MicroControls™ Linearity LQ Direct TIBC for Ortho Vitros 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): dTIBC.

The Audit MicroControls™ Linearity LQ Direct TIBC for Ortho Vitros 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 LQ Direct TIBC for Ortho Vitros 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.

Linearity LQ Direct TIBC for Ortho Vitros 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 LQ Direct TIBC for Ortho Vitros is an IVD device consisting of 5 levels of liquid material and additives in buffer solution.

Linearity LQ Direct TIBC for Ortho Vitros, 5 x 2 mL

STORAGE AND STABILITY

Linearity LQ Direct TIBC for Ortho Vitros 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 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 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 outside of 2-8°C storage should be minimized.

CALCULATIONS OF RESULTS

Each set of Linearity LQ Direct TIBC for Ortho Vitros 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 LQ Direct TIBC for Ortho Vitros should not be used for calibration or standardization of dTIBC 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.

To ensure results are consistent with target values, Linearity LQ Direct TIBC for Ortho Vitros should be used within five (5) days of opening/on-boarding a new reagent lot. Performance outside this window may result in decreased recovery.

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
K905M-5	Linearity LQ Direct TIBC for Ortho Vitros	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).

Analyte	Reagent, Instrument	Units	A	B	C	D	E
dTIBC	Ortho, Vitros	µg/dL	73.8	199	326	436	494



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