Linearity LQ TIBC for Ortho Vitros

REF **K905M-5**

5 x 2 mL

LOT 07148

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

IVD

2027-01-01

INTENDED USE

The Audit® MicroControls™ Linearity LQ TIBC for Ortho Vitros is intended to simulate human patient samples for determining linearity, calibration verification, and the verification of reportable range for the following analyte: TIBC.

This product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Linearity LQ TIBC for Ortho Vitros should not be used for calibration or standardization of the TIBC assay. The Linearity LQ 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 components[2]. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Linearity LQ TIBC for Ortho Vitros may be used as one would use human serum 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 LQ TIBC for Ortho Vitros is an IVD device consisting of 5 levels of liquid material and additives in a buffer.

Linearity LQ TIBC for Ortho Vitros, 5 x 2 mL

STORAGE AND STABILITY

Linearity LQ TIBC for Ortho Vitros is stored at 2-8°C and will remain stable in the unopened bottle 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 LQ TIBC for Ortho Vitros has an open bottle stability of up to 5 days under the proper storage conditions. Leaving the bottle uncapped, or prolonging its time at room temperature, will void this open bottle stability claim. Make sure the contents of the bottle 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 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 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 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 outisde of 2-8°C storage should be minimized.

CALCULATIONS OF RESULTS

Each set of Linearity LQ 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 recommendation[1] 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 LQ TIBC for Ortho Vitros should not be used for calibration or standardization of the TIBC assay.

If the contents of any of the bottles become frozen, discard all bottles and request a replacement set, as the results will not be valid.

Target values are intended only as guidelines. Laboratories should determine ranges based on their own test system and tolerance limit.

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
K905M-5	Linearity LQ 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).

	Units	Reagent, Instrument	A	B	C	D	E
Direct TIBC	µg/dL	Ortho, Ortho Vitros 5600	80	204	328	451	575

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

INS207 REV: 004
2025-08-06