CalVer LQ T-Uptake for Tosoh A1A

REF **K851M-5**
5 x 1 mL

LOT 07135A, 07135B, 07135C, 07135D, 07135E

Aalto Scientific Ltd
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USA

IVD

2027-04-10

ENGLISH

INTENDED USE

The CalVer LQ T-Uptake for Tosoh A1A is assayed quality control material consisting of five levels of human serum proteins. Each level contains the following analytes: T-uptake. CalVer LQ T-Uptake for Tosoh A1A is a quality control material intended for use in the quantitative verification of calibration and reportable range of the Tosoh T-uptake Assay when performed on the A1A Analyzer. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. CalVer LQ T-Uptake for Tosoh A1A 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. CalVer LQ T-Uptake for Tosoh A1A 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.

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.

CalVer LQ T-Uptake for Tosoh A1A 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

CalVer LQ T-Uptake for Tosoh A1A, 5 x 1 mL

STORAGE AND STABILITY

CalVer LQ T-Uptake for Tosoh A1A 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, CalVer LQ T-Uptake for Tosoh A1A has an open vial 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[1]:

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 CalVer LQ T-Uptake for Tosoh A1A is prepared in a manner such that an equal distance exists between each consecutive level.

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

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
K851M-5	CalVer LQ T-Uptake for Tosoh A1A	5 x 1 mL

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[1] Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1255, (b) (1) (ii).

Tosoh A1A						
	Units	A	B	C	D	E
T-Uptake	%	10.8	21.8	32.9	42.4	51.5

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

2025-05-30
INS147 REV: 006