Cal Ver LQ Blood Gas

REF K727M-5

15 x 2 mL

LOT 40350

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

2027-03-31

ENGLISH

INTENDED USE

The Cal Ver LQ Blood Gas is assayed quality control material consisting of five levels of buffers and salts in a bovine based material and equilibrated with known levels of Carbon Dioxide (CO2), Oxygen (O2), and Nitrogen. Each level contains the following analytes: pH, pCO2, pO2, Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Lactate, BUN, and Creatinine. The Cal Ver LQ Blood Gas is a quality control material intended for use in the quantitative verification of calibration and reportable range of pH, pCO2, pO2, Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Lactate, BUN, and Creatinine.

This product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Cal Ver LQ Blood Gas should not be used for calibration or standardization of the pH, pCO2, pO2, Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Lactate, BUN, and Creatinine assays. The Cal Ver LQ Blood Gas 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[1]. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Cal Ver LQ Blood Gas may be used as one would use human serum to verify and validate the AMR.

WARNINGS AND PRECAUTIONS

Cal Ver LQ Blood Gas 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

Cal Ver LQ Blood Gas, 15 x 2 mL

STORAGE AND STABILITY

Cal Ver LQ Blood Gas is stored at 2-8°C and will remain stable in the unopened ampule until the expiration date. After opening, the contents should be used according to the instrument manufacturer’s instructions.

When used to monitor the precision of laboratory testing procedures for its assays, Cal Ver LQ Blood Gas has an open ampule stability of up to 60 seconds. Delay in measuring the contents of an open ampule may cause room contamination and result in higher pO2 values than those stated. Make sure the contents of the ampule 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 ampule uncapped. Q.C. requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Calibration verification material should be run[2]:

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. Each ampule should be equilibrated at room temperature for at least 1 hour before use; open vials are stable for 1 minute.
2. Before sampling, hold the top of the ampule and shake gently. Then, with light tapping, restore all liquid to the bottom.
3. Break open carefully to avoid cutting of fingers.
4. Refer to instrument or assay instruction manual for verifying and validating the AMR.

CALCULATIONS OF RESULTS

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

Make sure that each ampule is brought to room temperature before testing. If the contents of any of the ampules become frozen, discard all ampules 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
K727M-5	Cal Ver LQ Blood Gas	15 x 2 mL

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[1] Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; p.3690.

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

	Units	Instrument / Reagent	1	2	3	4	5
BUN	mg/dL	Abbott iStat	77	45	21	7	4
Chloride	mEq/L	Abbott iStat	69	81	86	118	131
Creatinine	mg/dL	Abbott iStat	0.4	1.4	6.0	8.4	13.9
Glucose	mg/dL	Abbott iStat	461	340	142	80	35
Ionized Calcium	mmol/L	Abbott iStat	2.10	1.61	1.06	0.68	0.30
Lactate	mmol/L	Abbott iStat	18.2	5.2	2.5	0.8	0.3
Potassium	mEq/L	Abbott iStat	2.5	3.5	4.7	6.2	7.8
Sodium	mEq/L	Abbott iStat	104	121	137	158	173
pH	N/A	Abbott iStat	6.89	7.19	7.39	7.62	7.82
pCO2	mmHg	Abbott iStat	125	56	36	19	14
pO2	mmHg	Abbott iStat	50	81	116	163	407

REF Catalog Number

Use By (YYYY-MM-DD)

LOT Lot Number

www.auditmicro.com/inserts

2 – 8°C Temperature Limit

Manufactured By

INS138 REV: 009
2024-03-22