Audit® MicroCV™ Blood Gas Linearity Set

Cat. No. **K727M-5**
Contents 15 x 2 mL

Lot No. 90308

For In Vitro Diagnostic Use Only

Expires MARCH 31, 2012

INTENEDED USE

Audit® MicroCV™Blood Gas Linearity Set consists of five levels of buffers and salts in a bovine based material and are equilibrated with known levels of carbon dioxide (CO_2), oxygen (O_2) and nitrogen. Each level can be assayed for pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, BUN and creatinine. These five levels demonstrate a linear relationship to each other for their respective analytes, reagents and instruments[1].

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. Audit® Micro*CV*™ Blood Gas Linearity Set may be used as one would use human serum to verify and validate the AMR.

WARNINGS AND PRECAUTIONS

Audit® Micro*CV*™ Blood Gas Linearity Set is intended solely for in vitro diagnostic use for the purpose described on the labeling. Audit® MicroControls™, Inc. shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

Audit® Micro*CV*™ Blood Gas Linearity Set 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.

It is recommended that Audit® Micro*CV*™ Blood Gas Linearity Set be used within 60 seconds after opening. Delay in measuring the contents of an open ampule may cause room contamination and result in higher pO_2 values than those stated. Make sure the contents of the vial are well mixed before use.

MATERIALS PROVIDED

Audit® Micro*CV*™ Blood Gas Linearity Set , 15 x 2 mL

CALCULATIONS OF RESULTS

Each set of Audit® Micro*CV*™ Blood Gas Linearity Set is prepared in a manner such that an equal distance exists between each consecutive level. This dilution scheme is consistent with the NCCLS recommendation[1] for preparing linearity sets.

Once each ampule 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 vial is brought to room temperature at least one day before testing. 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. If the material becomes cloudy, do not use and bacterial contamination may be suspected.

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[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 one day before use.
2. Before actual sampling, hold ampule by the top and shake gently. Then with light tapping, restore all liquid to the bottom.
3. Break open carefully to avoid cutting of fingers. Use the complimentary ampule snapper provided with this test set.
4. Refer to instrument or assay instruction manual for verifying and validating the analytical measurement range.

EXPECTED VALUES

Each lot of product is manufactured such that a linear relationship exists among levels. 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	**Audit® Micro*CV*™ Blood Gas Linearity Set**	**15 x 2 mL**

[1] Dilution schemes are based on guidelines provided by The National Committee for Clinical Laboratory Standards (NCCLS) 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; §493.1255, (b) (1) (ii).

	UNITS	1	2	3	4	5
pH		6.845	7.195	7.415	7.555	7.730
pCO_2	mmHg	98	70	40	23	8.0
pO_2	mmHg	28	52	100	155	410
Sodium	mEq/L	100	122	142	158	185
Potassium	mEq/L	1.1	2.0	3.9	6.5	9.0
Chloride	mEq/L	65	90	115	135	155
Ionized Calcium	mmol/L	4.0	3.0	2.0	1.0	0.4
Glucose	mg/dL	50	90	190	385	520
Lactate	mmol/L	1.5	2.5	5.0	7.5	11.5
BUN	mg/dl	7.0	10.0	26	40	90
Creatinine	mg/dL	9.0	7.0	4.5	2.2	0.8