



BLOOD GAS / ISE LINEARITY TEST SET

Lot. No. 31206 Expiration: DEC 16

INTENDED USE

Phoenix Diagnostic's Blood Gas / Electrolyte Linearity Test Set is intended to monitor the performance of blood gas and ion-selective electrode instruments in measuring pH, PCO₂, PO₂, Na⁺, K⁺, Cl⁻, ionized calcium, magnesium, glucose, lactate, BUN, and creatinine. These calibration verification materials are intended for in vitro diagnostics use only.

SUMMARY & PRINCIPLE

The determination of acid base, blood gas, and electrolyte status in blood has become an integral part of the diagnosis and treatment of patients in intensive care units and surgery. Instruments that measure Blood Gas / Electrolyte parameters must meet stringent requirements for accuracy and precision. Phoenix Diagnostic's Blood Gas / ISE Linearity Test Set (when used as a part of a total control system) will assist clinicians in the documentation of instrumentation linearity, calibration verification and verification of linear range required by many inspection agencies.

PRODUCT DESCRIPTION

Phoenix Diagnostic's Blood Gas / ISE Linearity Test Sets are sealed in ampules containing buffers and salts in bovine serum matrix, and are equilibrated with known levels of carbon dioxide, oxygen, and nitrogen. Reagent grade chemicals of known quality and quantity are used in this material. Each test set prepared is formulated into 5 distinct levels, with 3 ampules per level, and 2mL per ampule.

STORAGE & STABILITY

Phoenix Diagnostic's Blood Gas / ISE Linearity Test Set should be stored at 2° to 8° Celsius. Avoid storing the product for prolonged periods of time in areas exposed to extreme fluctuations. Freezing of product will cause ampules to crack and / or affect product reliability. If stored at 2° to 8° Celsius, this product is stable for thirty-six months from date of manufacture. The lot number and expiration date are stamped on the ampules, package, and assay chart.

DIRECTIONS FOR USE

Phoenix Diagnostic's Blood Gas / ISE Linearity Test Set should be equilibrated at room temperature for at least one day before use. Before actual sampling, hold ampule by the top and shake gently. Then with light tapping, restore all liquid to the bottom. Break open carefully to avoid cutting of fingers – using the complementary ampule snapper provided with this test set.

For best results immediately aspirate liquid into analyzer (i.e. within 60 seconds). Delay in measuring contents of open ampule may cause room contamination and result in higher PO₂ values than those stated on the assay chart.

CALCULATION OF RESULTS

Simply enter data into our secured reduction web-based reduction program. To obtain username and password, please provide the information below to the following email address:

sales@phoenixdiagnostics.com

Company name, address, email address, type of kit purchased & provider

If you already have a username and password, simply log in to enter your data.

EXPECTED VALUES

The reference ranges for each parameter are assigned by multiple determinations performed on various makes and models of blood gas and electrolyte instruments listed in this assay sheet. The assigned values are determined with the product equilibrated at 25° Celsius and measured at 37° Celsius. If the instruments are properly calibrated, test data obtained while using our linearity test set should fall within expected ranges.

While each lot of product is manufactured in such a way that it will test the analytical measurement range of your instrument, actual results obtained may vary depending upon analyzer and methodology used, as well as assay temperature. Results may also depend upon the accuracy of the instrument and reagent calibration. The degree of acceptable non-linearity is an individual judgment based upon a test analyte's methodology, clinical significance and medical decision levels.

For this reason, technicians are advised to consult the analytical limits defined by the Clinical Laboratory Improvement Act of 1988 (CLIA '88). These criteria specify the *total error allowed* for most analytes in question, and they can be referenced at the following web address:

http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.931

LIMITATIONS

Phoenix Diagnostic's Blood Gas / ISE Linearity Test Set is sensitive to cuvette temperature, air contamination, calibration errors, and electrode drifts in blood gas systems. It is intended for use in evaluating the performance of laboratory instruments. It is not for use as a calibration standard, nor is it a substitute for other aspects of a complete quality control program.

BLOOD GAS/ ELECTROLYTE CALIBRATION VERIFICATION MATERIAL REFERENCE RANGES

MANUFACTURER/ INSTRUMENT	BLOOD GAS			ELECTROLYTES / METABOLITES								
	pH @ 37° C	PCO @ 37° C	PO @ 37° C	SODIUM	POTASSIUM	CHLORIDE	IONIZED CALCIUM	GLUCOSE	MAGNESIUM	BUN	CREATININE	LACTATE
		mmHg	mmHg	mEq/L	mEq/L	mEq/L	mmol/L	mg/dL	mmol/L	mg/dL	mg/dL	mmol/L
LEVEL 1 CHIRON® 200 Series 300 Series 600 Series 814, 834, 844, 854, 864 NOVA® Stat Profile Ultra NOVA 1-16 LI 1300 Series 1400 Series 1600 Series 1700 Series RADNOMETER® A, 30, 300, 330 S, 500 Series 600 Series 700 Series STAT EPOC AVL® 900 Series Omni Compact 9809/100 Series MALLINCKRODT® Gempremar	6.810-6.860	100-130	10-40	90-110	0.7-1.4	65-75	3.5-4.5	40-60				
LEVEL 2 CHIRON® 200 Series 300 Series 600 Series 814, 834, 844, 854, 864 NOVA® Stat Profile Ultra NOVA 1-16 LI 1300 Series 1400 Series 1600 Series 1700 Series RADNOMETER® A, 30, 300, 330 S, 500 Series 600 Series 700 Series AVL® 900 Series Omni Compact 9809/100 Series STAT EPOC MALLINCKRODT® Gempremar	7.130-7.180	70-90	55-80	115-130	1.5-2.5	87-97	2.7-3.7	70-110				
LEVEL 3 CHIRON® 200 Series 300 Series 600 Series 814, 834, 844, 854, 864 NOVA® Stat Profile Ultra NOVA 1-16 LI 1300 Series 1400 Series 1600 Series 1700 Series RADNOMETER® A, 30, 300, 330 S, 500 Series 600 Series 700 Series AVL® 900 Series Omni Compact 9809/100 Series STAT EPOC MALLINCKRODT® Gempremar	7.355-7.405	35-45	110-130	138-148	3.4-4.4	105-115	1.3-2.3	160-220				
LEVEL 4 CHIRON® 200 Series 300 Series 600 Series 814, 834, 844, 854, 864 NOVA® Stat Profile Ultra NOVA 1-16 LI 1300 Series 1400 Series 1600 Series 1700 Series RADNOMETER® A, 30, 300, 330 S, 500 Series 600 Series 700 Series AVL® 900 Series Omni Compact 9809/100 Series STAT EPOC MALLINCKRODT® Gempremar	7.530-7.580	16-26	160-180	160-170	6.0-7.0	115-125	0.5-1.5	350-420				
LEVEL 5 CHIRON® 200 Series 300 Series 600 Series 814, 834, 844, 854, 864 NOVA® Stat Profile Ultra NOVA 1-16 LI 1300 Series 1400 Series 1600 Series 1700 Series RADNOMETER® A, 30, 300, 330 S, 500 Series 600 Series 700 Series AVL® 900 Series Omni Compact 9809/100 Series STAT EPOC MALLINCKRODT® Gempremar	7.725-7.775	8-14	430-530	175-195	7.50-10.50	135-145	0.2-0.7	470-570				

1. Chiron
2. NOVA Biomedical, Waltham, MA 02254
3. Instrumentation Laboratory, Lexington, MA 02173
4. Radometer Copenhagen, The London Company, Westlake, OH 44145
5. AVL Scientific Corp., Roseville, GA 30077-0337
6. Mallinckrodt Sensor Systems, Ann Arbor, MI 48108