



BLOOD GAS / ISE LINEARITY TEST SET

Lot. No. 80107 Expiration: JAN 2011

INTENDED USE

Azer Scientific'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. Azer Scientific'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

Azer Scientific'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

Azer Scientific's Blood Gas / ISE Linearity Test Set should be stored at 2 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

Azer Scientific'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

Duplicate or triplicate runs are advised when obtaining a mean recovered value for each of the 5 levels provided in this test set. Once mean recovered value is obtained, plot results on standard linear graph paper using "Expected" as the X-axis and "Recovered" as the Y-axis. „Expected“ values will vary depending upon instrumentation in use. Please consult the included assay chart, for values most consistent with your own analyzer.

Users may also avail themselves of Azer Scientific's free data reduction service. By performing all of their calculations for them at no cost, we are able to save clinicians valuable time. Simply enter data into our customized MS Excel spreadsheets, and email them to the address provided. These sheets can be obtained by contacting us at the following address:

INFO@AZERSCIENTIFIC.COM

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

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

Azer Scientific'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

LEVEL 1

LEVEL 2

LEVEL 3

LEVEL 4

LEVEL 5

pH@ 37°C		PCO ₂ @ 37°C	PO ₂ @ 37°C	SODIUM	POTASSIUM	CHLORIDE	IONIZED CALCIUM	LITHIUM	GLUCOSE	MAGNESIUM	BU N	CREATININE LACTATE
MANUFACTURER / INSTRUMENT		mmHg	mmHg	mEq/L	mEq/L	mEq/L	mmol/L	mEq/L	mg/dL	mmol/L	mg/dL	mg/dL
CHIRON: 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	6.810-6.860	85-110	15-50				3.5-4.5					
	6.810-6.860	85-110	15-50				3.5-4.5					
	6.810-6.860	85-110	15-50	90-110 90-110	0.7-1.4 0.7-1.4	60-70 60-70	3.5-4.5					
	6.810-6.860	85-110	15-50	90-110 90-110	0.7-1.4 0.7-1.4	60-70 60-70	3.5-4.5		40-60			
NOVA: Stat Profile Ultra NOVA 1-16	6.820-6.870	85-110	15-50				3.5-4.5		40-60 40-60		6-8	8-10
	6.820-6.870	85-110	15-50	90-110 90-110	0.7-1.4 0.7-1.4	60-70 60-70	3.5-4.5	0-0.5 0-0.5			6-8	8-10 1-2 1-2
	6.820-6.870	85-110	15-50	90-110	0.7-1.4	60-70	3.5-4.5	0-0.5			6-8	8-10 1-2
IL: 1300 Series 1400 Series 1600 Series 1700 Series	6.820-6.870	90-115	15-50				3.5-4.5					
	6.820-6.870	90-115	15-50				3.5-4.5					
	6.820-6.870	90-115	15-50	90-110 90-110	0.7-1.4 0.7-1.4	60-70 60-70	3.5-4.5					
	6.820-6.870	90-115	15-50	90-110 90-110	0.7-1.4 0.7-1.4	60-70 60-70	3.5-4.5		40-60			
RADIOMETER: 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	6.820-6.870	85-110	15-50				3.5-4.5					
	6.820-6.870	85-110	15-50				3.5-4.5					
	6.820-6.870	85-110	15-50	90-110 90-110	0.7-1.4 0.7-1.4		3.5-4.5					
	6.820-6.870	85-110	15-50	90-110 90-110	0.7-1.4 0.7-1.4		3.5-4.5		40-60 40-60			
AVL: 900 Series Omni Compact 980/9100 Series	6.820-6.870	85-110	15-50				3.5-4.5					
	6.820-6.870	85-110	15-50				3.5-4.5		40-60		6-8	8-10 1-2
	6.820-6.870	85-110	15-50	90-110 90-110	0.7-1.4 0.7-1.4	60-70 60-70	3.5-4.5					
	6.820-6.870	85-110	15-50	90-110 90-110	0.7-1.4 0.7-1.4	60-70 60-70	3.5-4.5	0-0.5				
MALLINKRODT: Gempremier	< 6.80	85-110	15-50	90-110	0.7-1.4		> 5					
CHIRON: 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	7.165-7.215	60-80	45-70	115-130			2.5-3.5					
	7.165-7.215	60-80	45-70	115-130			2.5-3.5					
	7.165-7.215	60-80	45-70	115-130	1.5-2.5 1.5-2.5	85-95 85-95	2.5-3.5					
	7.165-7.215	60-80	45-70	115-130	1.5-2.5 1.5-2.5	85-95 85-95	2.5-3.5		70-110			
NOVA: Stat Profile Ultra NOVA 1-16	7.165-7.215	60-80	45-70	115-130			2.5-3.5	0.7-1.2	70-110 70-110		8-12	6-8
	7.165-7.215	60-80	45-70	115-130	1.5-2.5 1.5-2.5	85-95 85-95	2.5-3.5	0.7-1.2			8-12	6-8 2-3 2-3
	7.165-7.215	60-80	45-70	115-130	1.5-2.5	85-95	2.5-3.5	0.7-1.2			8-12	6-8 2-3
IL: 1300 Series 1400 Series 1600 Series 1700 Series	7.160-7.210	60-80	45-70	115-130			2.5-3.5					
	7.160-7.210	60-80	45-70	115-130			2.5-3.5					
	7.160-7.210	60-80	45-70	115-130	1.5-2.5 1.5-2.5	85-95 85-95	2.5-3.5					
	7.160-7.210	60-80	45-70	115-130	1.5-2.5 1.5-2.5	85-95 85-95	2.5-3.5		70-110			
RADIOMETER: 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	7.165-7.215	60-80	45-70	115-130			2.5-3.5					
	7.165-7.215	60-80	45-70	115-130			2.5-3.5					
	7.165-7.215	60-80	45-70	115-130	1.5-2.5 1.5-2.5		2.5-3.5					
	7.165-7.215	60-80	45-70	115-130	1.5-2.5 1.5-2.5		2.5-3.5		70-110 70-110			
AVL: 900 Series Omni Compact 980/9100 Series	7.170-7.220	60-80	50-75	115-130			2.5-3.5					
	7.170-7.220	60-80	50-75	115-130			2.5-3.5		70-110		8-12	6-8 2-3
	7.170-7.220	60-80	50-75	115-130	1.5-2.5 1.5-2.5	85-95 85-95	2.5-3.5					
	7.170-7.220	60-80	50-75	115-130	1.5-2.5 1.5-2.5	85-95 85-95	2.5-3.5	0.7-1.2				
MALLINKRODT: Gempremier	7.050-7.150	70-90	50-75	115-130	1.5-2.5		> 5					
CHIRON: 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	7.390-7.440	35-45	90-120	135-150		110-120	1.5-2.5					
	7.390-7.440	35-45	90-120	135-150		110-120	1.5-2.5					
	7.390-7.440	35-45	90-120	135-150	3.4-4.4 3.4-4.4	110-120	1.5-2.5					
	7.390-7.440	35-45	90-120	135-150	3.4-4.4 3.4-4.4	110-120	1.5-2.5		160-220			
NOVA: Stat Profile Ultra NOVA 1-16	7.380-7.430	35-45	15-50	135-150		110-120	1.5-2.5	1.3-1.8	160-220		23-29	
	7.380-7.430	35-45	15-50	135-150	3.4-4.4 3.4-4.4	110-120	1.5-2.5	1.3-1.8	160-220		9 4-5	
	7.380-7.430	35-45	15-50	135-150	3.4-4.4	110-120	1.5-2.5	1.3-1.8			23-29 4-5 4-6 4-6	
IL: 1300 Series 1400 Series 1600 Series 1700 Series	7.380-7.430	35-45	90-120	135-150		110-120	1.5-2.5					
	7.380-7.430	35-45	90-120	135-150		110-120	1.5-2.5					
	7.380-7.430	35-45	90-120	135-150	3.4-4.4 3.4-4.4	110-120	1.5-2.5					
	7.380-7.430	35-45	90-120	135-150	3.4-4.4 3.4-4.4	110-120	1.5-2.5		160-220			
RADIOMETER: 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	7.380-7.430	35-45	90-120	135-150			1.5-2.5					
	7.380-7.430	35-45	90-120	135-150			1.5-2.5					
	7.380-7.430	35-45	90-120	135-150	3.4-4.4 3.4-4.4		1.5-2.5					
	7.380-7.430	35-45	90-120	135-150	3.4-4.4 3.4-4.4		1.5-2.5		160-220			
AVL: 900 Series Omni Compact 980/9100 Series	7.380-7.430	35-45	90-120	135-150		110-120	1.5-2.5					
	7.380-7.430	35-45	90-120	135-150		110-120	1.5-2.5		160-220		23-29	4-5 4-6
	7.380-7.430	35-45	90-120	135-150	3.4-4.4 3.4-4.4	110-120	1.5-2.5					
	7.380-7.430	35-45	90-120	135-150	3.4-4.4 3.4-4.4	110-120	1.5-2.5	1.3-1.8				
MALLINKRODT: Gempremier	7.3-7.4	38-48	90-120	135-150	3.4-4.4		2.0-3.0					
CHIRON: 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	7.530-7.580	18-28	140-180	150-165		130-140	0.5-1.5					
	7.530-7.580	18-28	140-180	150-165		130-140	0.5-1.5					
	7.530-7.580	18-28	140-180	150-165	6.0-7.0 6.0-7.0	130-140	0.5-1.5		350-420			
	7.530-7.580	18-28	140-180	150-165	6.0-7.0 6.0-7.0	130-140	0.5-1.5					
NOVA: Stat Profile Ultra NOVA 1-16	7.530-7.580	18-28	140-180	150-165		130-140	0.5-1.5	1.8-2.2	350-420		35-45	2.0-2.5 6.5-8.5
	7.530-7.580	18-28	140-180	150-165	6.0-7.0 6.0-7.0	130-140	0.5-1.5	1.8-2.2	350-420		5 2.0-2.5 6.5-8.5	
	7.530-7.580	18-28	140-180	150-165	6.0-7.0	130-140	0.5-1.5	1.8-2.2			5 2.0-2.5 6.5-8.5	
IL: 1300 Series 1400 Series 1600 Series 1700 Series	7.530-7.580	18-28	140-180	150-165		130-140	0.5-1.5					
	7.530-7.580	18-28	140-180	150-165		130-140	0.5-1.5					
	7.530-7.580	18-28	140-180	150-165	6.0-7.0 6.0-7.0	130-140	0.5-1.5					
	7.530-7.580	18-28	140-180	150-165	6.0-7.0 6.0-7.0	130-140	0.5-1.5		350-420			
RADIOMETER: 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	7.530-7.580	18-28	140-180	150-165			0.5-1.5					
	7.530-7.580	18-28	140-180	150-165			0.5-1.5					
	7.530-7.580	18-28	140-180	150-165	6.0-7.0 6.0-7.0		0.5-1.5		350-420			
	7.530-7.580	18-28	140-180	150-165	6.0-7.0 6.0-7.0		0.5-1.5		350-420			
AVL: 900 Series Omni Compact 980/9100 Series	7.520-7.570	18-28	140-180	155-170		125-135	0.5-1.5					
	7.520-7.570	18-28	140-180	155-170		125-135	0.5-1.5		350-420		35-45	2.0-2.5 6.5-8.5
	7.520-7.570	18-28	140-180	155-170	6.0-7.0 6.0-7.0	125-135	0.5-1.5					
	7.520-7.570	18-28	140-180	155-170	6.0-7.0 6.0-7.0	125-135	0.5-1.5	1.8-2.2				
MALLINKRODT: Gempremier	7.520-7.570	18-28	140-180	155-170	6.5-7.5							
CHIRON: 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	7.700-7.760		375-475	175-195	7.50-10.50	150-160	0.2-0.7					
	7.700-7.760		375-475	175-195	7.50-10.50	150-160	0.2-0.7					
	7.700-7.760	5-11 5-11	375-475	175-195	7.50-10.50	150-160	0.2-0.7					
	7.700-7.760	5-11 5-11	375-475	175-195	7.50-10.50	150-160	0.2-0.7		470-570			
NOVA: Stat Profile Ultra NOVA 1-16	7.700-7.760		375-475	175-195	7.50-10.50	150-160	0.2-0.7	3.3-4.3	470-570		80-100	
	7.700-7.760											