

EVER Scientific

DIAGNOSTICS DIVISION

BLOOD GAS / ISE LINEARITY TEST SET

Lot. No. 50303

Expiration: MARCH 2008

INTENDED USE

Ever 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. Ever 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

Ever 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 5 ampules per level, and 2mL per ampule.

STORAGE & STABILITY

Ever Scientific'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

Ever 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 Ever 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. Spreadsheets can be downloaded from the following web location:

<http://www.eversci-linearity.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° 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

Ever 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/ISE CALIBRATION VERIFICATION MATERIAL REFERENCE RANGES

Lot. No. : 50303
Exp Date: MAR 08

	BLOOD GAS			ELECTROLYTES / METABOLITES									
	pH @ 37°C	pCO ₂ @ 37°C	pO ₂ @ 37°C	SODIUM	POTASSIUM	CHLORIDE	IONIZED CALCIUM	GLUCOSE	MAGNESIUM	BUN	CREATININE	LACTATE	
MANUFACTURER / INSTRUMENT		mmHg	mmHg	mmol/L	mmol/L	mmol/L	mmo/L	mg/dL	mmol/L	mg/dL	mg/dL	mmol/L	
LEVEL 1	CHIRON ¹ 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	6.865-6.915 6.865-6.915 6.865-6.915 6.865-6.915	85-110 85-110 85-110 85-110	15-50 15-50 15-50 15-50	88-102 88-102 88-102 88-102	0.7-1.4 0.7-1.4 0.7-1.4 0.7-1.4	55-65 55-65 55-65 55-65	2.5-3.5 2.5-3.5 2.5-3.5 2.5-3.5	40-60				
	NOVA ² Stat Profile Ultra NOVA 1-16	6.870-6.920 6.870-6.920 6.870-6.920	85-110 85-110 85-110	15-50 15-50 15-50	88-102 88-102 88-102	0.7-1.4 0.7-1.4 0.7-1.4	55-65 55-65 55-65	2.5-3.5 2.5-3.5 2.5-3.5	40-60 40-60 40-60	4.5 - 5.1 4.5 - 5.1 4.5 - 5.1	6-8 6-8 6-8	8-10 8-10 8-10	1-2 1-2 1-2
	IL ³ 1300 Series 1400 Series 1600 Series 1700 Series	6.870-6.920 6.870-6.920 6.870-6.920 6.870-6.920	90-115 90-115 90-115 90-115	15-50 15-50 15-50 15-50	88-102 88-102 88-102 88-102	0.7-1.4 0.7-1.4 0.7-1.4 0.7-1.4	55-65 55-65 55-65 55-65	2.5-3.5 2.5-3.5 2.5-3.5 2.5-3.5	40-60				
	RADIOMETER ⁴ 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	6.870-6.920 6.870-6.920 6.870-6.920 6.870-6.920	85-110 85-110 85-110 85-110	15-50 15-50 15-50 15-50	88-102 88-102 88-102 88-102	0.7-1.4 0.7-1.4 0.7-1.4 0.7-1.4	55-65 55-65 55-65 55-65	2.5-3.5 2.5-3.5 2.5-3.5 2.5-3.5	40-60 40-60				
	AVL ⁵ 900 Series Omni Compact 980/9100 Series	6.870-6.920 6.870-6.920 6.820-6.920 6.870-6.920	85-110 85-110 85-110 85-110	15-50 15-50 15-50 15-50	88-102 88-102 88-102 88-102	0.7-1.4 0.7-1.4 0.7-1.4 0.7-1.4	55-65 55-65 55-65 55-65	2.5-3.5 2.5-3.5 2.5-3.5 2.5-3.5	40-60		6-8	8-10	1-2
	MALLINKRODT ⁶ Gempremier	< 6.80	85-110	15-50	88-102	0.7-1.4		2.5-3.5					
	CHIRON ¹ 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	7.165-7.215 7.165-7.215 7.165-7.215 7.165-7.215	60-80 60-80 60-80 60-80	55-75 55-75 55-75 55-75	113-127 113-127 113-127 113-127	1.5-2.5 1.5-2.5 1.5-2.5 1.5-2.5	85-95 85-95 85-95 85-95	1.5-2.5 1.5-2.5 1.5-2.5 1.5-2.5	85-105				
	NOVA ² Stat Profile Ultra NOVA 1-16	7.165-7.215 7.165-7.215 7.165-7.215	60-80 60-80 60-80	55-75 55-75 55-75	113-127 113-127 113-127	1.5-2.5 1.5-2.5 1.5-2.5	85-95 85-95 85-95	1.5-2.5 1.5-2.5 1.5-2.5	85-105 85-105 85-105	3.1 - 3.7 3.1 - 3.7 3.1 - 3.7	8-12 8-12 8-12	6-8 6-8 6-8	2-3 2-3 2-3
	IL ³ 1300 Series 1400 Series 1600 Series 1700 Series	7.160-7.210 7.160-7.210 7.160-7.210 7.160-7.210	60-80 60-80 60-80 60-80	55-75 55-75 55-75 55-75	113-127 113-127 113-127 113-127	1.5-2.5 1.5-2.5 1.5-2.5 1.5-2.5	85-95 85-95 85-95 85-95	1.5-2.5 1.5-2.5 1.5-2.5 1.5-2.5	85-105				
	RADIOMETER ⁴ 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	7.165-7.215 7.165-7.215 7.165-7.215 7.165-7.215	60-80 60-80 60-80 60-80	55-75 55-75 55-75 55-75	113-127 113-127 113-127 113-127	1.5-2.5 1.5-2.5 1.5-2.5 1.5-2.5	85-95 85-95 85-95 85-95	1.5-2.5 1.5-2.5 1.5-2.5 1.5-2.5	85-105 85-105				
AVL ⁵ 900 Series Omni 980/9100 Series	7.170-7.220 7.170-7.220 7.170-7.220	60-80 60-80 60-80	60-80 60-80	113-127 113-127 113-127	1.5-2.5 1.5-2.5 1.5-2.5	85-95 85-95 85-95	1.5-2.5 1.5-2.5 1.5-2.5						
MALLINKRODT ⁶ Gempremier	7.050-7.150	70-90	60-80	113-127	1.5-2.5		1.5-2.5						
LEVEL 3	CHIRON ¹ 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	7.355-7.405 7.355-7.405 7.355-7.405 7.355-7.405	38-48 38-48 38-48 38-48	100-120 100-120 100-120 100-120	137-152 137-152 137-152 137-152	3.4-4.4 3.4-4.4 3.4-4.4 3.4-4.4	105-115 105-115 105-115 105-115	1.0-1.5 1.0-1.5 1.0-1.5 1.0-1.5	160-220				
	NOVA ² Stat Profile Ultra NOVA 1-16	7.350-7.400 7.350-7.400 7.350-7.400	38-48 38-48 38-48	100-120 100-120 100-120	137-152 137-152 137-152	3.4-4.4 3.4-4.4 3.4-4.4	105-115 105-115 105-115	1.0-1.5 1.0-1.5 1.0-1.5	160-220 160-220 160-220	2.1 - 2.7 2.1 - 2.7 2.1 - 2.7	23-29 23-29 23-29	4-5 4-5 4-5	4-6 4-6 4-6
	IL ³ 1300 Series 1400 Series 1600 Series 1700 Series	7.350-7.400 7.350-7.400 7.350-7.400 7.350-7.400	38-48 38-48 38-48 38-48	100-120 100-120 100-120 100-120	137-152 137-152 137-152 137-152	3.4-4.4 3.4-4.4 3.4-4.4 3.4-4.4	105-115 105-115 105-115 105-115	1.0-1.5 1.0-1.5 1.0-1.5 1.0-1.5	160-220				
	RADIOMETER ⁴ 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	7.350-7.400 7.350-7.400 7.350-7.400 7.350-7.400	38-48 38-48 38-48 38-48	100-120 100-120 100-120 100-120	137-152 137-152 137-152 137-152	3.4-4.4 3.4-4.4 3.4-4.4 3.4-4.4	105-115 105-115 105-115 105-115	1.0-1.5 1.0-1.5 1.0-1.5 1.0-1.5	160-220 160-220				
	AVL ⁵ 900 Series Omni Compact 980/9100 Series	7.350-7.400 7.350-7.400 7.350-7.400 7.350-7.400	38-48 38-48 38-48 38-48	100-120 100-120 100-120 100-120	137-152 137-152 137-152 137-152	3.4-4.4 3.4-4.4 3.4-4.4 3.4-4.4	110-120 110-120 110-120 110-120	1.0-1.5 1.0-1.5 1.0-1.5 1.0-1.5	160-220		23-29	4-5	4-6
	MALLINKRODT ⁶ Gempremier	7.3-7.4	40-50	100-120	137-152	3.4-4.4		1.0-1.5					
	CHIRON ¹ 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	7.570-7.620 7.570-7.620 7.570-7.620 7.570-7.620	18-28 18-28 18-28 18-28	160-190 160-190 160-190 160-190	150-165 150-165 150-165 150-165	5.5-6.5 5.5-6.5 5.5-6.5 5.5-6.5	120-130 120-130 120-130 120-130	0.4-0.8 0.4-0.8 0.4-0.8 0.4-0.8	270-310				
	NOVA ² Stat Profile Ultra NOVA 1-16	7.570-7.620 7.570-7.620 7.570-7.620	18-28 18-28 18-28	160-190 160-190 160-190	150-165 150-165 150-165	5.5-6.5 5.5-6.5 5.5-6.5	120-130 120-130 120-130	0.4-0.8 0.4-0.8 0.4-0.8	270-310 270-310 270-310	1.0 - 1.6 1.0 - 1.6 1.0 - 1.6	35-45 35-45 35-45	2.0-2.5 2.0-2.5 2.0-2.5	6.5-8.5 6.5-8.5 6.5-8.5
	IL ³ 1300 Series 1400 Series 1600 Series 1700 Series	7.570-7.620 7.570-7.620 7.570-7.620 7.570-7.620	18-28 18-28 18-28 18-28	160-190 160-190 160-190 160-190	150-165 150-165 150-165 150-165	5.5-6.5 5.5-6.5 5.5-6.5 5.5-6.5	120-130 120-130 120-130 120-130	0.4-0.8 0.4-0.8 0.4-0.8 0.4-0.8	270-310				
	RADIOMETER ⁴ 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	7.570-7.620 7.570-7.620 7.570-7.620 7.570-7.620	18-28 18-28 18-28 18-28	160-190 160-190 160-190 160-190	150-165 150-165 150-165 150-165	5.5-6.5 5.5-6.5 5.5-6.5 5.5-6.5	120-130 120-130 120-130 120-130	0.4-0.8 0.4-0.8 0.4-0.8 0.4-0.8	270-310 270-310				
AVL ⁵ 900 Series Omni Compact 980/9100 Series	7.560-7.610 7.560-7.610 7.560-7.610 7.560-7.610	18-28 18-28 18-28 18-28	160-190 160-190 160-190 160-190	150-165 150-165 150-165 150-165	5.5-6.5 5.5-6.5 5.5-6.5 5.5-6.5	120-130 120-130 120-130 120-130	0.4-0.8 0.4-0.8 0.4-0.8 0.4-0.8	270-310		35-45	2.0-2.5	6.5-8.5	
MALLINKRODT ⁶ Gempremier	7.560-7.610	18-28	160-190	150-165	5.5-6.5		0.4-0.8						
LEVEL 5	CHIRON ¹ 200 Series 300 Series 800 Series 614, 634, 644, 654, 664	7.700-7.760 7.700-7.760 7.700-7.760 7.700-7.760	8-14 8-14 8-14 8-14	450-550 450-550 450-550 450-550	170-190 170-190 170-190 170-190	8.0-10.0 8.0-10.0 8.0-10.0 8.0-10.0	135-145 135-145 135-145 135-145	0.2-0.4 0.2-0.4 0.2-0.4 0.2-0.4	370-430				
	NOVA ² Stat Profile Ultra NOVA 1-16	7.700-7.760 7.700-7.760 7.700-7.760	8-14 8-14 8-14	450-550 450-550 450-550	170-190 170-190 170-190	8.0-10.0 8.0-10.0 8.0-10.0	135-145 135-145 135-145	0.2-0.4 0.2-0.4 0.2-0.4	370-430 370-430 370-430	0.3 - 0.7 0.3 - 0.7 0.3 - 0.7	80-100 80-100 80-100	0.5-1.0 0.5-1.0 0.5-1.0	10-13 10-13 10-13
	IL ³ 1300 Series 1400 Series 1600 Series 1700 Series	7.700-7.760 7.700-7.760 7.700-7.760 7.700-7.760	8-14 8-14 8-14 8-14	450-550 450-550 450-550 450-550	170-190 170-190 170-190 170-190	8.0-10.0 8.0-10.0 8.0-10.0 8.0-10.0	135-145 135-145 135-145 135-145	0.2-0.4 0.2-0.4 0.2-0.4 0.2-0.4	370-430				
	RADIOMETER ⁴ 3, 30, 300, 330 5, 500 Series 600 Series 700 Series	7.700-7.760 7.700-7.760 7.700-7.760 7.700-7.760	8-14 8-14 8-14 8-14	450-550 450-550 450-550 450-550	170-190 170-190 170-190 170-190	8.0-10.0 8.0-10.0 8.0-10.0 8.0-10.0	135-145 135-145 135-145 135-145	0.2-0.4 0.2-0.4 0.2-0.4 0.2-0.4	370-430 370-430				
	AVL ⁵ 900 Series Omni Compact 980/9100 Series	7.700-7.760 7.700-7.760 7.700-7.760 7.700-7.760	8-14 8-14 8-14 8-14	450-550 450-550 450-550 450-550	170-190 170-190 170-190 170-190	8.0-10.0 8.0-10.0 8.0-10.0 8.0-10.0	135-145 135-145 135-145 135-145	0.2-0.4 0.2-0.4 0.2-0.4 0.2-0.4	370-430		80-100	0.5-1.0	10-13
	MALLINKRODT ⁶ Gempremier	7.700-7.760	8-14	450-550	170-190	8.0-10.0		0.2-0.4					

1. Chiron
2. NOVA Biomedical, Waltham, MA 02254
3. Instrumentation Laboratory, Lexington, MA 02173

4. Radiometer copenhagen, The London Company, Westlake, OH 44145
5. AVL Scientific Corp. Rosewell, GA 30017-0337
6. Mallinkrodt Sensor Systems, Ann Arbor, MI 48108