



BLOOD GAS / ELECTROLYTE CONTROL
Cat. No.: 1006A / 1007A / 1008A / 1009A
Lot. No.21204 EXP: DEC 15

Introduction

Phoenix Diagnostics' Blood Gas / Electrolyte Control is intended as a quality control material for use on all analyzers measuring pH, $p\text{CO}_2$, $p\text{O}_2$, Na^+ , K^+ , Cl^- , Ca^{++} , and Li^+ .

Summary and 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 and Electrolyte parameters must meet stringent requirements for accuracy and precision. Phoenix Diagnostics' Blood Gas / Electrolyte Control (when used as part of a total quality control system) will assist clinicians in monitoring the performance characteristics and calibration of their critical care instrumentation.

Product Description

Phoenix Diagnostics' Blood Gas / Electrolyte control is provided in sealed ampules containing buffers and salts in aqueous 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. These controls are formulated into 3 distinct levels that simulate distinct physiological ranges for each parameter:

Level 1 Acidosis / Level 2 Normal / Level 3 Alkalosis

Assigned 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 control set should fall within expected ranges. 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 variation is an individual judgment based upon a test analyte's methodology, clinical significance and medical decision levels. For this reason, it is recommended that each laboratory establish their own mean and standard deviation in accordance with daily laboratory practice.

Storage and Stability

Phoenix Diagnostics' Blood Gas / Electrolyte Control should be stored at 15° to 30° 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 15° to 30° 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 Diagnostics' Blood Gas / Electrolyte Control 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 tissue and gauze if necessary. 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 PO_2 values than those stated on the assay chart. While a direct aspiration technique minimizes air contamination of samples, this control may also be introduced to an instrument via syringe injection. After opening the ampule, aspirate the liquid immediately using a 3cc tuberculin syringe fitted with a 20-gauge needle. Once foam and air bubbles are expelled, remove the needle and inject liquid into the instrument.

Recommended Use

The three levels of Phoenix Diagnostics' Blood Gas / Electrolyte Control provides clinicians with a full range QC set that can be used to assess the performance characteristics of their instrumentation. These 3 levels should be run once every 8-hour shift and at any other time your instrument performance requires verification. If an analyzer has been shut down for an extended period, the use of control materials after calibration and before blood measurement is also recommended.

Limitations

Phoenix Diagnostics' Blood Gas / Electrolyte Control is sensitive to cuvette temperature, air contamination, calibration errors, and electrode drifts in Blood Gas / ISE systems. It is intended for use in evaluating the performance of laboratory instruments, and should not be considered as a substitute for other aspects of quality control such as calibration, recommended maintenance techniques and proper record keeping.

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Analyzer	pH	pCO2	pO2	Na+	K+	Cl-	Ca++	Li+
		mmHg	mmHg	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
LEVEL 1								
Bayer (Corning / Chiron)								
200 Series	7.165-7.225	62-74	64-84	116-126	1.70-2.70	82-92	2.20-2.60	
348 Rapidlab Series	7.160-7.220	62-74	64-84	116-126	1.70-2.70	82-92	2.20-2.60	
800 Rapidlab Series	7.170-7.230	62-74	64-84	116-126	1.70-2.70	82-92	2.20-2.60	
600 Electrolyte Series	7.17-7.23							0.35-0.65
Diametrics								
IRMA SL								
Instrumentation Labs								
1300 Series	7.155-7.215	58-70	65-85	113-123	1.6-2.6			
BG3 & BGE	7.165-7.225	60-72	67-87	113-123	1.6-2.6	82-92		
1600 Series	7.165-7.225	64-76	64-84	113-123	1.6-2.6	82-92	2.20-2.60	
Synthesis Series	7.165-7.225	60-72	63-83	115-125	1.7-2.7	85-92	2.20-2.60	
Gem Premier	7.17-7.23	68-80	58-78	115-125	1.7-2.7		2.30-2.70	
Medica								
EasyBloodGas	7.160-7.220	65-77	64-84	116-126	1.60-2.60	85-95	2.30-2.70	
EasyStat	7.160-7.220	63-75	64-84	116-126	1.60-2.60		2.30-2.70	
Nova								
Stat Profile 1-10	7.180-7.240	66-78	69-89	116-126	1.70-2.70	82-92	2.30-2.70	0.35-0.65
Stat Profile Ultra	7.180-7.240	66-78	69-89	116-126	1.70-2.70	82-92	2.30-2.70	0.35-0.65
pHOx	7.190-7.250	66-78	72-92					
Osmetech								
OPTI 1	7.164-7.225	62-74	67-87					
OPTI CCA	7.190-7.250	62-74	69-89	116-126	1.80-2.80	90-100	2.25-2.65	
Radiometer								
3, 30, 300, 330								
5, 500 Series	7.165-7.225	62-74	72-92	116-126	1.60-2.60			
600 & EML Series	7.160-7.220	62-74	72-92	116-126	1.60-2.60	82-92		
700 Series	7.160-7.220	62-74	74-94	116-126	1.60-2.60	82-92		
800 Series	7.165-7.225	60-72	76-96	116-126	1.60-2.60	82-92		
ICA, KNA 1				116-126	1.60-2.60		2.20-2.60	
Roche / AVL								
900 Series	7.150-7.210	62-74	75-95					
Omni 1-9	7.150-7.210	62-74	75-95	116-126	1.60-2.60	85-95	2.35-2.75	
Compact Series	7.150-7.210	62-74	75-95					
980 & 9100 Electrolyte Series					1.60-2.60	80-90	2.20-2.60	0.35-0.65
LEVEL 2								
Bayer (Corning / Chiron)								
200 Series	7.350-7.410	34-46	114-134					
348 Rapidlab Series	7.350-7.410	34-46	114-134	135-145	3.50-4.50	100-110	0.80-1.20	
800 Rapidlab Series	7.360-7.420	34-46	114-134	135-145	3.50-4.50	100-110	0.80-1.20	
600 Electrolyte Series	7.35-7.41			135-145	3.50-4.50	100-110	0.80-1.20	0.65-1.05
Diametrics								
IRMA SL								
Instrumentation Labs								
1300 Series	7.350-7.410	32-44	114-134	135-145	3.40-4.40			
BG3 & BGE	7.350-7.410	34-46	114-134	135-145	3.40-4.40	100-110		
1600 Series	7.350-7.410	33-45	109-129	135-145	3.40-4.40	100-110		
Synthesis Series	7.350-7.410	35-47	112-132	135-145	3.40-4.40	100-110		
Gem Premier	7.36-7.42	34-46	104-124	130-140	3.3-4.3		0.80-1.20	
Medica								
EasyBloodGas	7.340-7.400	38-48	109-129	135-145	3.3-4.3	100-110	0.80-1.20	
EasyStat	7.340-7.400	38-48	109-129	135-145	3.3-4.3		0.80-1.20	
Nova								
Stat Profile 1-10	7.35-7.41	33-45	122-142	130-140	3.5-4.5	100-110	0.80-1.20	0.65-1.05
Stat Profile Ultra	7.35-7.41	33-45	122-142	130-140	3.5-4.5	100-110	0.80-1.20	0.65-1.05
pHOx	7.36-7.42	33-45	122-142					
Osmetech								
OPTI 1	7.340-7.400	37-49	124-134					
OPTI CCA	7.350-7.410	37-49	122-132	132-142	3.6-4.6	105-115	0.85-1.25	
Radiometer								
3, 30, 300, 330								
5, 500 Series	7.340-7.400	35-47	116-136	130-140	3.50-4.50			
600 & EML Series	7.340-7.400	34-46	116-136	130-140	3.50-4.50	95-105		
700 Series	7.340-7.400	34-46	116-136	130-140	3.50-4.50	95-105		
800 Series	7.340-7.400	34-46	116-136	130-140	3.50-4.50	95-105		
ICA, KNA 1				130-140	3.50-4.50	95-105	0.80-1.20	
Roche / AVL								
900 Series	7.340-7.400	35-47	119-139					
Omni 1-9	7.340-7.400	35-47	119-139	135-145	3.6-4.6	98-108	0.80-1.20	
Compact Series	7.340-7.400	35-47	119-139					
980 & 9100 Electrolyte Series					3.4-4.4	95-105	0.80-1.20	0.65-1.05
LEVEL 3								
Bayer (Corning / Chiron)								
200 Series	7.560-7.620	18-28	165-185					
348 Rapidlab Series	7.560-7.620	18-28	165-185	153-163	6.10-7.10	125-135	0.25-0.55	
800 Rapidlab Series	7.570-7.630	18-28	165-185	153-163	6.10-7.10	125-135	0.25-0.55	
600 Electrolyte Series	7.52-7.62			153-163	6.10-7.10	125-135	0.25-0.55	1.60-2.00
Diametrics								
IRMA SL								
Instrumentation Labs								
1300 Series	7.570-7.630	19-29	166-186					
BG3 & BGE	7.570-7.630	19-29	166-186	151-161	5.9-6.9	120-130		
1600 Series	7.570-7.630	19-29	165-185	151-161	5.9-6.9	120-130		
Synthesis Series	7.570-7.630	20-30	166-186	151-161	5.9-6.9	120-130		
Gem Premier	7.62-7.68	16-26	160-180	158-168	6.2-7.2		0.15-0.45	
Medica								
EasyBloodGas	7.550-7.600	17-27	170-190	153-163	5.8-6.8	117-127	0.20-0.60	
EasyStat	7.550-7.600	17-27	170-190	153-163	5.8-6.8		0.20-0.60	
Nova								
Stat Profile 1-10	7.57-7.63	16-26	180-200	156-166	6.9-7.9	117-127	0.20-0.60	1.60-2.00
Stat Profile Ultra	7.57-7.63	16-26	180-200	156-166	6.9-7.9	117-127	0.20-0.60	1.60-2.00
pHOx	7.59-7.65	17-27	170-190					
Osmetech								
OPTI 1	7.600-7.660	15-25	180-200					
OPTI CCA	7.590-7.650	15-25	180-200	154-164	5.6-6.6	120-130	0.20-0.60	
Radiometer								
3, 30, 300, 330								
5, 500 Series	7.555-7.615	18-28	162-182	152-162	6.60-7.60			
600 & EML Series	7.555-7.615	17-27	160-180	152-162	6.60-7.60	115-125		
700 Series	7.555-7.615	17-27	160-180	152-162	6.60-7.60	115-125		
800 Series	7.555-7.615	17-27	160-180	152-162	6.60-7.60	115-125		
ICA, KNA 1				152-162	6.60-7.60		0.20-0.60	
Roche / AVL								
900 Series	7.550-7.610	17-27	170-190					
Omni 1-9	7.550-7.610	17-27	170-190	158-168	6.6-7.6	120-130	0.20-0.60	
Compact Series	7.550-7.610	17-27	170-190	158-168				
980 & 9100 Electrolyte Series				158-168	6.6-7.6	117-127	0.25-0.55	1.60-2.00