

Introduction

Phoenix Diagnostics' Blood Gas / Electrolyte / Metabolite 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⁻, Li⁺, Mg⁺⁺, Ca⁺⁺, BUN, Glucose, Creatinine, and Lactate.

Summary and Principle

The determination of acid base, Blood Gas, Electrolyte, and Metabolite 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, and Metabolite parameters must meet stringent requirements for accuracy and precision. Phoenix Diagnostics' Blood Gas / Electrolyte / Metabolite 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 / Metabolite control is provided in sealed 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. 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 / Metabolite Control 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 Diagnostics' Blood Gas / Electrolyte / Metabolite 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 PO₂ 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 / Metabolite 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 / Metabolite 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.

Analyzer	pH	pCO2	pO2	Na+	K+	Cl-	Ca++	Li+	Mg++	Glucose	BUN	Creatinine	Lactate	
		mmHg	mmHg	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	mg/dL	mmol/L	
LEVEL 1	Bayer (Corning / Chiron)													
	200 Series	7.090-7.150	68-82	60-80	115-125	1.5-2.5	87-97	2.20-2.70						
	348 Rapidlab Series	7.090-7.150	68-82	60-80	115-125	1.5-2.5	87-97	2.20-2.70						
	800 Rapidlab Series	7.090-7.150	68-82	60-80	115-125	1.5-2.5	87-97	2.20-2.70		80-120				
	600 Electrolyte Series	7.090-7.150			115-125	1.5-2.5	87-97	2.20-2.70	0.60-1.00				5.0-7.0	
	Diametrics													
	IRMA SL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Instrumentation Labs													
	1300 Series	7.090-7.150	58-72	61-81										
	BG3 & BGE	7.090-7.150	61-76	62-82	115-125	1.4-2.4								
	1600 Series	7.090-7.150	68-81	60-80	115-125	1.5-2.5	86-96	2.20-2.70						
	Synthesis Series	7.090-7.150	62-74	59-79	114-124	1.6-2.6	92-102	2.20-2.70			80-120			
	Gem Premier	7.080-7.160	69-83	65-85	120-130	1.6-2.6		2.20-2.70						
	Medica													
	EasyBloodGas	7.080-7.140	70-84	60-80										
	EasyStat	7.080-7.140	68-82	60-80	116-126	1.5-2.5		2.20-2.70						
	Nova													
	Stat Profile 1-10	7.100-7.160	64-78	60-80	117-127	1.6-2.6	91-101	2.25-2.75	0.60-1.00	2.0-3.0	85-125	7-11	5.5-7.5	5.0-7.0
	Stat Profile Ultra	7.105-7.165	65-79	58-78	117-127	1.6-2.6	91-101	2.25-2.75	0.60-1.00	2.0-3.0	85-125	7-11	5.5-7.5	5.0-7.0
	pHOx	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Osmetech													
	OPTI 1	7.090-7.150	66-80	68-88										
	OPTI CCA	7.120-7.180	67-81	75-85	118-128	1.6-2.6	98-108	2.10-2.60			85-125			
	Radiometer													
	3, 30, 300, 330	7.090-7.150	64-78	58-78										
	5, 500 Series	7.090-7.150	66-80	60-80	117-127	1.5-2.5	86-96	2.25-2.75						
	600 & EML Series	7.090-7.150	67-81	60-80	117-127	1.5-2.5	86-96	2.25-2.75			75-115			5.0-7.0
	700 Series	7.090-7.150	64-78	60-80	117-127	1.5-2.5	88-98	2.25-2.75			75-115			5.0-7.0
	ICA, KNA 1				116-126	1.5-2.5		2.20-2.70						
	Roche / AVL													
900 Series	7.080-7.140	66-80	65-85											
Omni 1-9	7.080-7.140	66-80	63-83	117-127	1.5-2.5	97-107	2.10-2.60			82-122	7-11	5.5-7.5	5.0-7.0	
Compact Series	7.080-7.140	70-84	67-87											
980 & 9100 Electrolyte Series				116-126	1.5-2.5	91-101	2.10-2.60	0.60-1.00						
LEVEL 2	Bayer (Corning / Chiron)													
	200 Series	7.280-7.340	34-44	100-120	134-144	3.6-4.6	97-117	1.00-1.40						
	348 Rapidlab Series	7.280-7.340	35-45	97-117	135-145	3.6-4.6	97-117	1.00-1.40						
	800 Rapidlab Series	7.280-7.340	35-45	97-117	135-145	3.6-4.6	97-117	1.00-1.40		200-240				
	600 Electrolyte Series	7.280-7.340			137-147	3.6-4.6	97-117	1.00-1.40	0.25-0.45				2.50-3.50	
	Diametrics													
	IRMA SL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Instrumentation Labs													
	1300 Series	7.280-7.340	33-43	100-120										
	BG3 & BGE	7.280-7.340	35-45	100-120	135-145	3.5-4.5	93-113	1.0-1.40						
	1600 Series	7.280-7.340	34-44	95-115	136-146	3.5-4.5		1.0-1.40						
	Synthesis Series	7.280-7.340	35-45	98-118	137-147	3.7-4.7	97-117	1.0-1.40			190-230			
	Gem Premier	7.280-7.340	37-47	110-130	143-153	3.7-4.7		1.0-1.40						
	Medica													
	EasyBloodGas	7.280-7.340	36-46	100-120										
	EasyStat	7.280-7.340	37-47	102-122	139-149	3.5-4.5								
	Nova													
	Stat Profile 1-10	7.280-7.340	34-44	100-120	137-147	3.7-4.7	96-116	0.90-1.30	0.25-0.45	1.0-2.0	200-240		22-28	2.50-3.50
	Stat Profile Ultra	7.290-7.350	34-44	100-120	137-147	3.7-4.7	96-116	0.90-1.30	0.25-0.45	1.0-2.0	200-240		22-28	2.50-3.50
	pHOx	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Osmetech													
	OPTI 1	7.280-7.340	35-45	105-125										
	OPTI CCA	7.290-7.350	34-44	102-122	142-152	3.8-4.8	100-120	0.90-1.30			210-250			
	Radiometer													
	3, 30, 300, 330	7.280-7.340	33-43	107-127										
	5, 500 Series	7.280-7.340	33-43	105-125	136-146	3.6-4.6	92-112	1.00-1.40						
	600 & EML Series	7.280-7.340	33-43	105-125	136-146	3.6-4.6	92-112	1.00-1.40			190-230			2.50-3.50
	700 Series	7.280-7.340	31-41	103-123	137-147	3.7-4.7	93-113	1.00-1.40			190-230			2.50-3.50
	ICA, KNA 1				126-136	3.8-4.8		0.90-1.30						
	Roche / AVL													
900 Series	7.290-7.350	33-43	105-125											
Omni 1-9	7.280-7.340	33-43	103-123	142-152	3.8-4.8	102-122	0.90-1.30			190-230		22-28	2.50-3.50	
Compact Series	7.280-7.340	35-45	107-127											
980 & 9100 Electrolyte Series				140-150	3.7-4.7	97-117	0.90-1.30	0.25-0.45						
LEVEL 3	Bayer (Corning / Chiron)													
	200 Series	7.450-7.510	17-25	155-175	150-170	5.4-6.4	116-136	0.30-0.70						
	348 Rapidlab Series	7.450-7.510	16-24	160-180	150-170	5.4-6.4	116-136	0.30-0.70						
	800 Rapidlab Series	7.450-7.510	16-24	160-180	150-170	5.4-6.4	116-136	0.30-0.70		350-450				
	600 Electrolyte Series	7.450-7.510			150-170	5.4-6.4	116-136	0.30-0.70	1.00-1.40				0.40-1.40	
	Diametrics													
	IRMA SL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Instrumentation Labs													
	1300 Series	7.450-7.510	18-26	162-182										
	BG3 & BGE	7.460-7.520	18-26	162-182	148-168	5.1-6.1	111-131	0.35-0.75						
	1600 Series	7.460-7.520	16-24	160-180	148-168	5.1-6.1	111-131	0.35-0.75						
	Synthesis Series	7.460-7.520	18-26	161-181	148-168	5.4-6.4	113-133	0.35-0.75			330-430			
	Gem Premier	7.460-7.520	16-24	165-185	153-173	5.2-6.2		0.35-0.75						
	Medica													
	EasyBloodGas	7.450-7.510	16-24	168-188	151-171									
	EasyStat	7.450-7.510	18-26	169-189	153-173	5.2-6.2		0.40-0.80						
	Nova													
	Stat Profile 1-10	7.460-7.520	16-24	165-185	150-170	5.4-6.4	116-136	1.00-1.40	0.50-1.00	0.50-1.00	330-430		32-42	0.40-1.40
	Stat Profile Ultra	7.460-7.520	16-24	164-184	150-170	5.4-6.4	116-136	1.00-1.40	0.50-1.00	0.50-1.00	330-430		32-42	0.40-1.40
	pHOx	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Osmetech													
	OPTI 1	7.470-7.530	14-22	162-182	149-169									
	OPTI CCA	7.470-7.530	14-22	157-177	149-169	5.2-6.2	121-141	0.35-0.75						
	Radiometer													
	3, 30, 300, 330	7.450-7.510	16-24	165-185										
	5, 500 Series		16-24	160-180	148-168	5.2-6.2	111-131	0.35-0.75						
	600 & EML Series	7.450-7.510	15-23	161-181	148-168	5.2-6.2	111-131	0.35-0.75			310-410			0.40-1.40
	700 Series	7.450-7.510	15-23	158-178	148-168</									