BLOOD GAS / ELECTROLYTE / METABOLITE CONTROL

Cat. No.: 1006A / 1007A / 1008A / 1009A

Lot No:40700 EXP: JUL 17

Introduction

Phoenix Diagnostics' Blood Gas / Electrolyte / Metabolite Control is intended as a quality control material for use on all analyzers measuring pH, pCO_2, pO_2, Na+, K+, Cl-, Ca++, Li+, Mg++, LAC, GLU, BUN, and CREAT.

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, 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 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 / Metabolite Control should be stored at 2° to 8° Celsius. This control may be stored unopened at room temperature (20 to 25°C) for 12 months, but do not expose it to temperatures below 2°C or above 30°C. Do not store in direct sunlight. 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°-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. This product is shipped under ambient conditions.

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 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 / 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.

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PHOENIX DIAGNOSTICS

BLOOD GAS/ELECTROLYTE/METABOLITE

Cat. No. 1006A/1007A/1008A/1009A

LOT 40700

2°C 8°C

JUL 17

	Analyser	pH	pCO2 mmHg	pO2 mmHg	Na+ mmol/L	K+ mmol/L	Cl- mmol/L	Ca++ mmol/L	Li+ mmol/L	Mg++ mmol/L	LAC mmol/L	GLU mg/dL	BUN mg/dL	CREAT mg/dL
LEVEL 1	**Siemens**													
	200 Series	7.17-7.23	54-70	65-85										
	348 Rapidlab Series	7.17-7.23	55-71	49-69	114-124	1.4-2.4	76-86	2.0-2.8						
	800 Rapidlab Series	7.18-7.24	56-70	54-74	114-124	1.4-2.4	76-86	2.0-2.8			4.5-5.5	270-330		
	600 Electrolyte Series	7.18-7.24			115-125	1.4-2.4	76-86	2.0-2.8						
	1200 Rapidlab Series	7.18-7.24	56-70	50-70	114-124	1.4-2.4	76-86	2.0-2.8			4.5-5.5	270-330		
	Convergent													
	Convergys ISE/BG	7.18-7.24	54-68	61-81	119-129	1.5-2.5	80-90	2.3-3.1	0.45-0.65					
	Diametrics													
	IRMA SL	7.18-7.24	56-70	50-70	114-124	1.4-2.4	76-86	2.0-2.8						
	Instrumentation Labs													
	1600 Series	7.16-7.22	58-72	55-73	116-126	1.3-2.3		2.2-3.0						
	Synthesis Series	7.16-7.22	56-70	55-73	116-126	1.3-2.3		2.1-2.9						
	Gem Premier	7.13-7.21	55-73	63-87	113-123	1.2-2.2		2.1-2.9						
	Medica													
	EasyBloodGas	7.18-7.24	54-68	61-81	119-129	1.5-2.5	80-90	2.3-3.1	0.45-0.65					
	Easystat	7.18-7.24			119-129	1.5-2.5	80-90	2.3-3.1	0.45-0.65					
	Nova													
	Stat Profile 1-10	7.20-7.26	54-68	58-76	116-126	1.4-2.4	75-85	2.4-3.2		2.8-3.2	4.5-5.5	270-330	35-45	2.5-3.5
	Stat Profile Ultra	7.20-7.26	55-69	56-76	116-126	1.4-2.4	75-85	2.4-3.2		2.8-3.2	4.5-5.5	270-330	35-45	2.5-3.5
	pHOx	7.20-7.26	55-69	56-76	116-126	1.4-2.4	75-85	2.4-3.2		2.8-3.2	4.5-5.5	270-330	35-45	2.5-3.5
	Osmetech													
	OPTI 1	7.20-7.26	55-69	56-76	116-126	1.4-2.4	75-85	2.4-3.2			4.5-5.5	270-330	35-45	
	OPTI CCA	7.20-7.26	55-69	56-76	116-126	1.4-2.4	75-85	2.4-3.2			4.5-5.5	270-330	35-45	
	Radiometer													
	5, 500 Series	7.16-7.22	54-68	65-85										
	600 & EML Series	7.16-7.22	54-68	65-85										
	700 Series	7.16-7.22	54-68	65-85	116-126	1.4-2.4	75-85	2.4-3.2			4.5-5.5	270-330		
	800 Series	7.16-7.22	54-68	65-85	116-126	1.4-2.4	75-85	2.4-3.2			4.5-5.5	270-330		
	ICA, KNA 1	7.16-7.22	54-68	65-85	116-126	1.4-2.4		2.4-3.2						
	Roche/ AVL													
	900 Series													
	Omni 1-9	7.17-7.23	56-70	50-70			80-90	2.0-2.8						
	Compact Series	7.17-7.23	56-70	80-100										
	Roche Cobas b 121	7.17-7.23	56-70	50-70	116-126	1.4-2.4	75-85	2.4-3.2			4.5-5.5	270-330		
	Eschweiler				118-128	1.5-2.5	80-90	2.3-3.1	0.45-0.65		4.5-5.5	270-330		
	Combiine	7.19-7.25	54-68	61-81	118-128	1.5-2.5	80-90	2.3-3.1	0.45-0.65		4.5-5.5	270-330		
	Combisys II	7.19-7.25	53-67	61-81	118-128	1.5-2.5	80-90	2.3-3.1	0.45-0.65		4.5-5.5	270-330		
	Ecolyte	7.18-7.24			118-128	1.5-2.5	80-90	2.3-3.1	0.45-0.65		4.5-5.5	270-330		
	Ecosys II	7.19-7.25	53-67	61-81	119-129	1.5-2.5	80-90	2.3-3.1	0.45-0.65		4.5-5.5	270-330		
	Modular Pro	7.18-7.24	54-68	61-81										
	Abbott													
	i-Stat	7.20-7.26	55-69	56-76	116-126	1.4-2.4	75-85	2.4-3.2		2.8-3.2	4.5-5.5	270-330	35-45	2.5-3.5
	Alere													
	Epoc	7.20-7.26	55-69	56-76	116-126	1.4-2.4	75-85	2.4-3.2		2.8-3.2	4.5-5.5	270-330	35-45	2.5-3.5
LEVEL 2	**Siemens**				138-148									
	200 Series	7.40-7.46	34-46	94-114	140-150	3.7-4.7	93-103	1.1-1.4						
	348 Rapidlab Series	7.39-7.45	35-47	87-107	140-150	3.7-4.7	95-105	1.1-1.4			2.5-3.5	120-180		
	800 Rapidlab Series	7.41-7.47	36-46	95-115	140-150	3.7-4.7	93-103	1.1-1.4						
	600 Electrolyte Series	7.40-7.46			140-150	3.7-4.7	95-105	1.1-1.4			2.5-3.5	120-180		
	1200 Rapidlab Series	7.41-7.47	36-46	93-113	140-150	3.7-4.7	95-105	1.1-1.4			2.5-3.5	120-180		
	Convergent				141-151	4.0-5.0	102-112	1.2-1.5	0.88-1.08					
	Convergys ISE/BG	7.39-7.45	35-45	97-117										
	Diametrics				140-150	3.7-4.7	95-105	1.1-1.4						
	IRMA SL	7.41-7.47	36-46	93-113										
	Instrumentation Labs				139-149	3.7-4.7		1.2-1.5						
	1600 Series	7.37-7.43	36-46	96-114	139-149	3.7-4.7	92-102	1.2-1.5						
	Synthesis Series	7.38-7.44	34-44	93-111	140-150	3.8-4.8	92-102	1.2-1.5						
	Gem Premier	7.39-7.47	33-47	99-121										
	Medica				141-151	4.0-5.0	102-112	1.2-1.5	0.88-1.08					
	EasyBloodGas	7.39-7.45	35-45	97-117	141-151	4.0-5.0	102-112	1.2-1.5	0.88-1.08					
	Easystat	7.39-7.45												
	Nova													
	Stat Profile 1-10	7.40-7.46	34-44	93-111	140-150	3.5-4.5		1.3-1.6		1.3-1.7	2.5-3.5	120-180	23-29	1.2-1.8
	Stat Profile Ultra	7.41-7.47	35-45	91-111	140-150	3.5-4.5		1.3-1.6		1.3-1.7	2.5-3.5	120-180	23-29	1.2-1.8
	pHOx	7.41-7.47	35-45	91-111	140-150	3.5-4.5		1.3-1.6		1.3-1.7	2.5-3.5	120-180	23-29	1.2-1.8
	Osmetech				140-150	3.5-4.5		1.3-1.6			2.5-3.5	120-180	23-29	
	OPTI 1	7.41-7.47	35-45	91-111	140-150	3.5-4.5		1.3-1.6			2.5-3.5	120-180	23-29	
	OPTI CCA	7.41-7.47	35-45	91-111	140-150	3.5-4.5		1.3-1.6			2.5-3.5	120-180	23-29	
	Radiometer													
	5, 500 Series	7.38-7.44	34-44	95-113										
	600 & EML Series	7.38-7.44	35-45	100-118	138-148	3.8-4.8	90-100	1.3-1.8			2.5-3.5	120-180		
	700 Series	7.38-7.44	35-45	100-118	138-148	3.8-4.8	90-100	1.3-1.8			2.5-3.5	120-180		
	800 Series	7.38-7.44	35-45	100-118	138-148	3.8-4.8		1.3-1.8						
	ICA, KNA 1	7.38-7.44	35-45	100-118										
	Roche/ AVL													
	900 Series							1.3-1.8						
	Omni 1-9	7.37-7.44	38-48	100-118										
	Compact Series	7.37-7.41	38-48	115-133										
	Roche Cobas b 121	7.37-7.41	38-48	100-118	138-148	3.8-4.8	90-100	1.3-1.8			2.5-3.5	120-180		
	Eschweiler				141-151	4.0-5.0	101-111	1.2-1.5	0.88-1.08		3.0-3.5	120-180		
	Combiine	7.39-7.45	34-44	97-117	141-151	4.0-5.0	101-111	1.2-1.5	0.88-1.08		3.0-3.5	120-180		
	Combisys II	7.39-7.45	34-44	97-117	141-151	4.0-5.0	101-111	1.2-1.5	0.88-1.08		3.0-3.5	120-180		
	Ecolyte	7.39-7.45	34-44		141-151	4.0-5.0	101-111	1.2-1.5	0.88-1.08		3.0-3.5	120-180		
	Ecosys II	7.39-7.45		97-117	141-151	4.0-5.0	102-112	1.2-1.5	0.88-1.08		3.0-3.5	120-180		
	Modular Pro	7.39-7.45	35-45	97-117										
	Abbot													
	i-Stat	7.41-7.47	35-45	91-111	140-150	3.5-4.5	101-111	1.3-1.6		1.3-1.7	2.5-3.5	120-180	23-29	1.2-1.8
	Alere													
	EPOC	7.41-7.47	35-45	91-111	140-150	3.5-4.5	101-111	1.3-1.6		1.3-1.7	2.5-3.5	120-180	23-29	1.2-1.8
LEVEL 3	**Siemens**													
	200 Series	7.59-7.65	20-30	157-179	156-166									
	348 Rapidlab Series	7.59-7.65	21-31	158-180	156-166	6.2-7.2	115-125	0.4-0.6						
	800 Rapidlab Series	7.60-7.66	21-29	163-185	155-165	6.2-7.2	115-125	0.4-0.6			0.6-1.0	35-65		
	600 Electrolyte Series	7.59-7.65				6.2-7.2	115-125	0.4-0.6						
	1200 Rapidlab Series	7.60-7.66	22-30	160-180	155-165	6.2-7.2	115-125	0.4-0.6			0.6-1.0	35-65		
	Convergent													
	Convergys ISE/BG	7.59-7.65	20-28	161-181	153-163	6.2-7.2	117-127	0.4-0.7	2.15-2.65					
	Diametrics													
	IRMA SL	7.60-7.66	22-30	160-180	155-165	6.2-7.2	115-125	0.4-0.6						
	Instrumentation Labs													
	1600 Series	7.57-7.63	22-30	166-186	151-161	6.1-7.1								
	Synthesis Series	7.57-7.63	20-28	166-186	151-161	6.1-7.1	114-124	1.2-1.5				35-65		
	Gem Premier	7.62-7.70	17-29	166-192	156-166	6.2-7.2	114-124	1.2-1.5				35-65		
	Medica													
	EasyBloodGas	7.59-7.65	20-28	161-181	153-163	6.2-7.2	117-127	0.4-0.7	2.15-2.65					
	Easystat	7.59-7.65			153-163	6.2-7.2	117-127	0.4-0.7	2.15-2.65					
	Nova													
	Stat Profile 1-10	7.59-7.65	20-28	168-188										0.3-0.7
	Stat Profile Ultra	7.61-7.67	21-29	165-187	152-162	6.2-7.2	113-123	0.5-0.8		0.3-0.7	0.6-1.0	35-65	6-10	0.3-0.7
	pHOx	7.61-7.67	21-29	165-187	152-162	6.2-7.2	113-123	0.5-0.8		0.3-0.7	0.6-1.0	35-65	6-10	0.3-0.7
	Osmetech				152-162	6.2-7.2	113-123	0.5-0.8		0.3-0.7	0.6-1.0	35-65	6-10	
	OPTI 1	7.61-7.67	21-29	165-187										
	OPTI CCA	7.61-7.67	21-29	165-187	152-162	6.2-7.2	113-123	0.5-0.8			0.6-1.0	35-65	6-10	
	Radiometer				152-162	6.2-7.2	113-123	0.5-0.8			0.6-1.0	35-65	6-10	
	5, 500 Series	7.58-7.64	20-28	168-188										
	600 & EML Series	7.58-7.64	20-28	172-192										
	700 Series	7.58-7.64	20-28	172-192	149-159	6.3-7.3	115-125	0.4-0.7			0.6-1.0	35-65		
	800 Series	7.58-7.64	20-28	172-192	149-159	6.3-7.3	115-125	0.4-0.7			0.6-1.0	35-65		
	ICA, KNA 1	7.58-7.64	20-28	172-192	149-159	6.3-7.3		0.4-0.7						
	Roche/ AVL													
	900 Series													
	Omni 1-9	7.59-7.65	20-28	170-190			120-130	0.4-0.7						
	Compact Series	7.59-7.65	20-28	185-205										
	Roche Cobas b 121	7.59-7.65	20-28	170-190										
	Eschweiler				149-159	6.3-7.3	115-125	0.4-0.7			0.6-1.0	35-65		
	Combiine	7.59-7.65	19-27	161-181	152-162	6.3-7.3	117-127	0.4-0.7	2.15-2.65			35-65		
	Combisys II	7.59-7.65	19-27	160-180	152-162	6.3-7.3	117-127	0.4-0.7	2.15-2.65		0.6-1.0	35-65		
	Ecolyte	7.59-7.65			152-162	6.3-7.3	117-127	0.4-0.7	2.15-2.65		0.6-1.0	35-65		
	Ecosys II	7.59-7.65	19-27	160-180	152-162	6.3-7.3	117-127	0.4-0.7	2.15-2.65		0.6-1.0	35-65		
	Modular Pro	7.59-7.65	20-28	161-181	153-163	6.2-7.2	117-127	0.4-0.7	2.15-2.65		0.6-1.0	35-65		
	Abbot													
	iStat	7.61-7.67	21-29	165-187	152-162	6.2-7.2	113-123	0.5-0.8		0.3-0.7	0.6-1.0	35-65	6-10	0.3-0.7
	Alere													
	EPOC	7.61-7.67	21-29	165-187	152-162	6.2-7.2	113-123	0.5-0.8		0.3-0.7	0.6-1.0	35-65	6-10	0.3-0.7

IVD

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