

MISSION CONTROL™
Blood Gas and Electrolyte Control

Level 2
 PN: DD-92002D

LOT: MC-1019
 Exp: 2011/03

Expected Ranges Chart

Blood Gas/ISE Analyzers	pH			pCO ₂ mmHg			pO ₂ mmHg			Na ⁺ mmol/L			K ⁺ mmol/L			Ca ⁺⁺ mmol/L			Cl ⁻ mmol/L			Li ⁺ mmol/L			tCO ₂ mmol/L			
	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
AVL Scientific/Roche																												
945, 947	7.328	7.269	7.387	49	43	55	101	83	120																			
990, 995	7.328	7.269	7.387	49	43	55	99	81	117																			
Compact Series	7.338	7.279	7.397	50	44	56	99	81	117																			
982, 983, 985										138	131	145	4.17	3.83	4.50			105	97	113	1.02	0.90	1.14					
986										142	135	149	4.27	3.93	4.61			106	98	115				34	30	38		
984, 987	7.338	7.279	7.397							138	131	145	4.27	3.93	4.61	1.06	0.90	1.22										
OMNI	7.348	7.289	7.407	49	43	55	91	75	108	137	130	144	4.17	3.83	4.50	1.07	0.91	1.23	107	98	116							
Cobas b 121	7.378	7.319	7.437	49	43	55	87	71	104	137	130	144	4.17	3.83	4.50	1.00	0.84	1.16	107	98	116							
Cobas b 221	7.368	7.309	7.427	49	43	55	86	70	103	137	130	144	4.17	3.83	4.50	1.00	0.84	1.16	107	98	116							
9110, 9140	7.348	7.289	7.407							133	126	140	4.17	3.83	4.50	1.05	0.89	1.21										
9120, 9130										133	126	140	3.97	3.65	4.29			107	99	116								
9180, 9181										134	127	141	3.97	3.65	4.29	1.07	0.91	1.23	100	92	108	1.11	0.98	1.24				
Ciba-Corning/Bayer/Siemens																												
238	7.36	7.30	7.42	49	43	55	93	77	110																			
248	7.358	7.299	7.417	49	43	55	88	72	104																			
348	7.373	7.314	7.432	49	43	55	96	79	114	134	127	140	4.07	3.74	4.39	1.07	0.91	1.23	103	95	111							
278	7.368	7.309	7.427	49	43	55	96	79	114																			
280	7.368	7.309	7.427	49	43	55	96	79	114																			
288	7.368	7.309	7.427	49	43	55	96	79	114	133	126	139	4.07	3.74	4.39	1.07	0.91	1.23	103	95	111							
664										135	128	142	4.07	3.74	4.39			103	95	111				34	30	38		
614, 644										134	127	140	4.07	3.74	4.39			103	95	111								
634	7.38	7.32	7.44												1.12	0.95	1.29											
654										134	127	140	4.07	3.74	4.39								1.03	0.91	1.15			
800 Series*	7.385	7.326	7.444	49	43	55	97	80	115	134	127	141	4.07	3.74	4.39	1.02	0.87	1.17	96	88	104							
Rapid 400, 405	7.378	7.319	7.437	49	43	55	97	80	115	131	124	137	4.07	3.74	4.39	1.08	0.92	1.24	105	96	113							
Diamond																												
GemLyte										134	127	141	4.14	3.81	4.47	1.10	0.94	1.27	96	89	104	1.01	0.89	1.14				
proLYTE										136	129	143	4.22	3.88	4.55			94	87	102								
IL																												
1304, 1306, 1312	7.348	7.289	7.407	48	43	54	96	79	114																			
BG3	7.348	7.289	7.407	49	43	55	95	78	113																			
BGE	7.348	7.289	7.407	49	43	55	94	77	111	132	125	138	3.87	3.56	4.18	1.10	0.94	1.27	103	94	111							
1610, 1620	7.348	7.289	7.407	49	43	55	96	79	114																			
1630, 1640, 1650	7.348	7.289	7.407	49	43	55	95	78	112	134	127	140	3.87	3.56	4.18	1.10	0.94	1.27	103	94	111							
Synthesis 10, 15, 20, 25	7.348	7.289	7.407	45	40	51	101	83	120	134	127	140	3.83	3.52	4.13	1.10	0.94	1.27	103	95	111							
Synthesis 30, 35, 40, 45	7.348	7.289	7.407	45	40	51	101	83	120	134	127	140	3.83	3.52	4.13	1.10	0.94	1.27	103	95	111							
GEM Premier	7.347	7.288	7.405	50	44	56	99	81	117	136	129	143	3.97	3.65	4.29	1.12	0.95	1.29										
GEM 3000	7.347	7.288	7.405	50	44	56	99	81	117	136	129	143	3.97	3.65	4.29	1.12	0.95	1.29										
ITC																												
IRMA TRUpoint	7.37	7.32	7.43	49	43	55	105	86	123																			
NOVA																												
Electrolyte Systems	7.358	7.299	7.417							136	129	143	4.17	3.83	4.50	1.06	0.90	1.22	103	95	111	1.09	0.96	1.22	34	30	38	
Stat Profile 1-5	7.358	7.299	7.417	49	43	55	91	75	108	135	128	142	4.17	3.83	4.50	1.06	0.90	1.22	103	94	111							
Stat Profile pHox series	7.406	7.381	7.431	40	37	43	112	106	118	133	129	137	4.20	3.95	4.45	1.09	1.01	1.17	95	90	99							
Osmetech/OptiMedical																												
Opti 1	7.42	7.36	7.48	48	42	54	98	80	115																			
Opti CCA	7.42	7.36	7.48	49	43	55	96	78	113	138	131	145	4.21	3.87	4.54	1.01	0.86	1.16	106	98	115							
Opti LION	7.38	7.31	7.45							131	128	134	4.21	3.87	4.54	1.01	0.81	1.21	106	95	118							
Opti R	7.41	7.35	7.47	51	45	57	105	87	122	139	132	146	4.31	3.97	4.64	1.05	0.90	1.20										
Radiometer																												
ABL 3, 30	7.358	7.299	7.417	48	43	54	99	81	117																			
ABL 300, 330	7.358	7.299	7.417	48	43	54	96	79	114																			
ABL 5	7.34	7.28	7.40	48	43	54	95	78	112																			
ABL, 50, 500, 510, 520	7.348	7.289	7.407	47	41	53	105	86	124																			
ABL 505	7.348	7.289	7.407	47	41	53	99	81	117	133	126	139	4.07	3.74	4.39	1.08	0.92	1.24										
ABL555	7.348	7.289	7.407	47	41	53	99	81	116	133	127	140	4.05	3.73	4.38	1.08	0.92	1.24										
ABL 600, 610, 620	7.348	7.289	7.407	47	41	53	98	81	116	133	126	139	4.07	3.74	4.39	1.08	0.92	1.24	101	93	109							
ABL 70, 77	7.36	7.30	7.42	48	42	54	95	78	112	136	129	143	4.15	3.82	4.49	1.05	0.89	1.21	99	91	107							
ABL 700 Series**	7.348	7.289	7.407	49	43	55	93	77	110	133	126	139	4.07	3.74	4.39	1.08	0.92	1.24	100	92	108							
ABL 800 Series***	7.346	7.287	7.405	48	42	54	95	79	112	133	126	139	4.07	3.74	4.39	1.08	0.92	1.24	102</									

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
 Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: MISSION CONTROL™ Blood Gas and Electrolyte Control is an assayed quality control material intended for monitoring the measurements of pH pCO₂, pO₂ in blood gas analyzers and sodium, potassium, chloride, lithium, ionized calcium and total carbon dioxide in ISE electrolyte analyzers.

Product Description: This control material is provided for monitoring analyzer performance. It is packaged in sealed glass ampules, each containing approximately 2 ml of solution. Ampules are packaged 10 per tray with each box containing 3 trays, for a total of 30 ampules per box.

Active Ingredients: MISSION CONTROL™ is a buffered solution of electrolytes (Na⁺, K⁺, Cl⁻, Ca⁺⁺, Li⁺, HCO₃⁻/CO₃⁻²). It has been equilibrated with specific levels of CO₂, O₂, and N₂. This control contains no human-based materials.

For in vitro diagnostics use.

Directions for Use

The control should be brought to a temperature of 20-23°C before use (see instructions regarding Expected Ranges). Allow at least four (4) hours for ampules to equilibrate to this temperature prior to testing.

For pH/blood gas values, the control should be analyzed within one (1) minute of opening. For electrolyte measurements, this product is stable for up to one (1) hour after opening.

Follow the procedures listed below:

1. Before use, hold the ampule at the top and bottom (with forefinger and thumb) and shake 15-20 times (about 10 seconds) to mix the solution. Tap the ampule to restore the liquid to the bottom on the ampule.
2. Open the ampule by snapping off the tip at the score. Use gauze, tissue, gloves, or an appropriate ampule opener to protect fingers from cuts.
3. Immediately introduce the liquid from the ampule to the analyzer. Follow the manufacturer's instructions for sampling a control material. Depending on the sampling procedure chosen, the following instructions apply:
 - a. Direct Aspiration: Sample the control directly from the ampule.
 - b. Syringe Transfer:
 - i. Use a clean, gas-tight syringe attached to a clean, blunt syringe needle (if available).
 - ii. Prime the syringe by slowly aspirating a small amount (0.2-0.3 ml) of solution from the ampule.
 - iii. Discard this liquid, leaving the dead space of the syringe filled with the control.
 - iv. Aspirate the control from the ampule into the primed syringe. Be careful that air is not drawn in with the liquid. Expel 1 to 2 drops, detach the needle and immediately inject the control into the analyzer sample port.
 - c. Ampule Injector/Dispenser: Assemble and fill the ampule injector following the manufacturer's instructions. Expel one or two drops to rinse the outlet tip and inject the control into the analyzer sample port.
 - d. Capillary Mode:
 - i. Install the appropriate adapter for micro sampling onto the instrument.
 - ii. Sample the contents of the ampule following the recommendations of the instrument manufacturer. Be certain to keep the sampling tip of the adapter below the surface of the liquid during aspiration.

Limitations
Limitation:

1. This control is sensitive to many instrument related factors that affect analytical results. Because it is not a blood-based material, it may not detect certain malfunctions, which would affect the testing of blood.
2. This product is intended for use as a quality control material and can assist in evaluating the performance of laboratory instruments. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.

Storage:

Store at 18-25°C. Avoid freezing and exposure to temperatures greater than 30°C. You may also store at 4-25°C without adverse effect.

Expected Ranges:

The values for each control analyte on the enclosed Expected Ranges Chart are based on multiple determinations performed on randomly selected samples from each lot. The listing for each instrument represents the expected range for these ampules when tested at 23°C. (Note: pO₂ values will vary inversely by about one percent (1%) per degree C that the temperature of the ampules varies from 23°C.

The Expected Ranges are provided as a guide in evaluating analyzer performance. Since instrument design and operating conditions may vary, each laboratory should establish its own expected values and control limits. The mean value established should fall within the Expected Ranges shown on the chart.

