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 pCo_2, pO_2 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^+, HCO_3^-/CO_3^{-2}). It has been equilibrated with specific levels of CO_2, O_2, and N_2. 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.

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MISSION CONTROL™
Blood Gas and Electrolyte Control
Level 3
PN: DD-92003D

LOT: MC-1023
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	7.603	7.542	7.664	23	20	26	138	122	155																		
990, 995	7.603	7.542	7.664	23	20	26	134	118	150																		
Compact Series	7.613	7.552	7.674	23	20	25	131	115	147																		
982, 983, 985										166	158	175	7.1	6.55	7.69				119	110	129	2.10	1.85	2.35			
986										167	158	175	7.1	6.55	7.69				119	110	129				25	21	29
984, 987	7.608	7.548	7.669							167	158	175	7.1	6.55	7.69	0.64	0.54	0.73									
OMNI	7.598	7.538	7.659	23	20	26	123	109	138	165	156	173	7.0	6.46	7.58	0.58	0.49	0.66	120	111	130						
Cobas b 121	7.598	7.538	7.659	22	19	25	122	108	137	163	154	171	6.6	6.06	7.18	0.54	0.45	0.62	121	112	131						
Cobas b 221	7.588	7.528	7.649	23	20	26	122	108	137	163	154	171	6.6	6.06	7.18	0.54	0.45	0.62	119	110	129						
9110, 9140	7.608	7.548	7.669							158	150	166	6.8	6.24	7.32	0.60	0.51	0.69									
9120, 9130										158	150	166	7.0	6.46	7.58				120	111	130						
9180, 9181										158	150	166	7.0	6.46	7.58	0.58	0.49	0.66	118	109	128	2.24	1.97	2.51			
Ciba-Corning/Bayer/Siemens																											
238	7.63	7.57	7.69	23	20	25	117	103	132																		
248	7.628	7.567	7.689	24	21	27	118	104	133																		
348	7.648	7.587	7.709	22	20	25	128	113	144	160	152	168	7.0	6.46	7.58	0.53	0.45	0.61	117	108	127						
278	7.628	7.567	7.689	22	20	25	128	113	144																		
280	7.628	7.567	7.689	22	20	25	128	113	144																		
288	7.628	7.567	7.689	22	20	25	129	114	145	167	158	175	7.0	6.46	7.58	0.53	0.45	0.61	117	108	127						
664										167	158	175	6.8	6.28	7.37				118	109	128				25	21	29
614, 644										167	158	175	6.8	6.28	7.37				118	109	128						
634	7.66	7.60	7.72													0.56	0.47	0.64									
654										167	158	175	6.9	6.37	7.47							2.10	1.85	2.35			
800 Series*	7.658	7.597	7.719	25	22	28	124	110	139	159	151	167	6.9	6.37	7.47	0.50	0.42	0.57	118	109	128						
Rapid 400, 405	7.658	7.597	7.719	23	20	25	124	110	139	167	158	175	6.9	6.37	7.47	0.50	0.42	0.57	118	109	128						
Diamond																											
GemLyte										157	149	165	6.6	6.07	7.13	0.68	0.58	0.78	117	108	126	2.00	1.76	2.24			
proLYTE										159	151	166	6.8	6.24	7.33				115	105	124						
iL																											
1304, 1306, 1312	7.598	7.538	7.659	24	21	27	126	111	142																		
BG3	7.608	7.548	7.669	23	20	25	126	111	142																		
BGE	7.618	7.557	7.679	24	21	27	125	110	141	164	156	172	6.6	6.09	7.15	0.59	0.50	0.68	114	105	123						
1610, 1620	7.618	7.557	7.679	22	20	25	126	111	142																		
1630, 1640, 1650	7.618	7.557	7.679	22	19	24	124	110	139	164	156	172	6.6	6.09	7.15	0.58	0.49	0.66	114	105	123						
Synthesis 10, 15, 20, 25	7.608	7.547	7.669	24	21	27	126	111	141	164	155	172	6.8	6.25	7.33	0.58	0.49	0.66	114	105	123						
Synthesis 30, 35, 40, 45	7.608	7.547	7.669	24	21	27	126	111	141	164	155	172	6.8	6.25	7.33	0.58	0.49	0.66	114	105	123						
Gem Premier	7.618	7.557	7.679	22	19	24	129	114	145	164	156	172	6.6	6.09	7.15	0.58	0.49	0.66									
GEM 3000	7.618	7.557	7.679	22	19	24	129	114	145	164	156	172	6.6	6.09	7.15	0.58	0.49	0.66									
ITC																											
IRMA TRUpoint	7.66	7.60	7.72	23	20	25	137	120	153																		
NOVA																											
Electrolyte Systems	7.635	7.574	7.697							170	162	179	7.7	7.10	8.34	0.55	0.47	0.63	117	108	127	2.13	1.87	2.38	27	23	31
Stat Profile 1-5	7.618	7.557	7.679	23	20	25	129	114	145	168	159	176	6.9	6.37	7.47	0.58	0.49	0.66	117	108	127						
Stat Profile pHOx series	7.696	7.671	7.721	21	18	24	139	129	149	157	153	161	6.61	6.31	6.91	0.77	0.71	0.83	115	111	120						
Osmetech/OptiMedical																											
Opti 1	7.71	7.65	7.77	23	20	25	127	112	143																		
Opti CCA	7.71	7.65	7.77	23	20	25	125	110	141	167	158	175	7.5	6.92	8.12	0.57	0.49	0.66	118	109	128						
Opti LION	7.66	7.60	7.72							163	157	168	7.7	7.12	8.32	0.77	0.62	0.93	115	104	127						
Opti R	7.71	7.65	7.77	22	19	24	133	118	149	172	163	180	7.8	7.22	8.42	0.78	0.70	0.87									
Radiometer																											
ABL 3, 30	7.628	7.567	7.689	22	20	25	133	117	150																		
ABL 300, 330	7.628	7.567	7.689	23	20	26	131	115	147																		
ABL 5	7.62	7.56	7.68	22	20	25	129	114	145																		
ABL, 50, 500, 510, 520	7.628	7.567	7.689	23	20	25	133	117	149																		
ABL 505	7.628	7.567	7.689	22	20	25	133	117	149	165	156	173	6.8	6.28	7.37	0.59	0.50	0.68									
ABL 555	7.628	7.567	7.689	22	20	25	133	117	149	165	156	173	6.8	6.28	7.37	0.59	0.50	0.68									
ABL 600, 610, 620	7.628	7.567	7.689	22	20	25	133	117	149	165	156	173	6.7	6.18	7.26	0.59	0.50	0.68	112	103	121						
ABL 70,77	7.63	7.57	7.69	23	20	26	127	112	142	162	154	170	6.8	6.23	7.31	0.59	0.50	0.68	115	106	124						
ABL 700 Series**	7.618	7.557	7.679	22	20	25	130	114	146	165	156	173	6.8	6.28	7.37	0.59	0.50	0.68	112	103	121						
ABL 800 Series***	7.609	7.548	7.670	22	20	25	133	117	149	165	156	173	6.8	6.28	7.37	0.61	0.52	0.70	112	103	121						
EML-100										158	150	164	6.7	6.18	7.26	0.67	0.58	0.76	106	97	115						
i-STAT																											
BG, E+	7.648	7.587	7.710	23	20	25	124	109	139	165	156	173	6.8	6.28	7.37	0.59	0.50	0.68	112	103	121						
Medica, ILyte, Menarini																											
EasyElectrolytes										162	154	170	6.4	5.89	6.95				117	108	126	2.26	1.99	2.53			
EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/pH/Ca	7.625	7.564	7.686							160	152	168	6.6	6.09	7.15	0.73	0.62	0.84	118	109	127	2.24	1.97	2.51			
ISE Module										163	155	171	6.4	5.89	6.95				118	109	127	2.28	2.01	2.55			

*Includes 840, 845, 850, 855, 860 Analyzers

**Includes 705, 710, 715, 720, 725

***Includes 805, 810, 815, 820, 825, 830, 835, Basic