

**MISSION COMPLETE™**  
**Blood Gas and Electrolyte Linearity**

**Level 5**

PN: DD-92905

Expected Ranges Chart

LOT: R7H162

Exp: 2010/07

Blood Gas/ISE Analyzers	pH			pCO2 mmHg			pO2 mmHg			Na+ mmol/L			K+ mmol/L			Ca++ mmol/L			Cl- mmol/L			Glucose mg/dL			Lact 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
<b>AVL Scientific</b>																											
945, 947	7.786	7.746	7.826	10	6	14	417	357	477																		
990, 995	7.786	7.746	7.826	11	7	15	431	371	491																		
Compact Series	7.806	7.766	7.846	10	6	14	426	366	486																		
982, 983, 985										154	149	159	1.6	1.3	2.3			125	120	130							
986										154	149	159	1.6	1.3	2.3			125	120	130							
984, 987	7.786	7.746	7.826							154	149	159	1.6	1.3	2.3	0.40	0.30	-0.50									
OMNI	7.776	7.736	7.816	11	7	15	387	327	447	153	148	158	1.5	1.0	2.0	0.33	0.23	-0.43	126	121	131	0	0	5	11.7	9.2	14.2
9110, 9140	7.786	7.746	7.826							153	148	158	1.5	1.0	2.0	0.40	0.30	-0.50									
9120, 9130										153	148	158	1.5	1.0	2.0				126	121	131						
9180, 9181										153	148	158	1.5	1.0	2.0	0.33	0.23	-0.43	126	121	131						
<b>Ciba-Corning/Bayer</b>																											
238	7.816	7.776	7.856	10	6	14	417	357	477																		
248	7.816	7.776	7.856	10	6	14	417	357	477																		
348	7.816	7.776	7.856	10	6	14	432	372	492	149	144	154	0.9	0.4	1.4	0.30	0.20	-0.40	124	119	129						
278	7.816	7.776	7.856	10	6	14	432	372	492																		
280	7.816	7.776	7.856	10	6	14	432	372	492																		
288	7.816	7.776	7.856	10	6	14	437	377	497	149	144	154	1.0	0.5	1.5	0.30	0.20	-0.40	124	119	129						
664										149	144	154	1.4	0.9	1.9				124	119	129						
614, 644										150	145	155	1.4	0.9	1.9				125	120	130						
634	7.82	7.78	7.86												0.30	0.20	-0.40										
654										150	145	155	1.4	0.9	1.9												
800 Series*	7.836	7.796	7.876	9	5	13	402	342	462	150	145	155	0.9	0.4	1.4	0.33	0.23	-0.43	125	120	130	0	0	5	9.8	7.3	12.3
Rapid 400, 405	ORL			ORL			387	327	447	150	145	155	1.0	0.5	1.5	0.33	0.23	-0.43	125	120	130	0	0	5			
<b>IL</b>																											
1304, 1306, 1312	7.786	7.746	7.826	12	8	16	417	357	477																		
BG3	7.796	7.756	7.836	10	6	14	427	367	487																		
BGE	7.796	7.756	7.836	11	7	15	427	367	487	147	142	152	1.2	0.7	1.7	0.33	0.23	-0.43	121	116	126						
1610, 1620	7.796	7.756	7.836	9	5	13	417	357	477																		
1630, 1640, 1650	7.796	7.756	7.836	9	5	13	417	357	477	149	144	154	1.2	0.7	1.7	0.33	0.23	-0.43	121	116	126						
Synthesis 10, 15, 20, 25	7.796	7.756	7.836	10	6	14	447	387	507	148	143	153	1.6	1.1	2.1	0.30	0.20	-0.40	121	116	126	0	0	5			
GEM Premier	ORL			10	4	16	409	349	469	153	148	158	1.6	1.1	2.1	0.33	0.23	-0.43									
GEM 3000	ORL			12	8	16	427	367	487	153	148	158	1.6	1.1	2.1	0.33	0.23	-0.43									
<b>ITC</b>																											
IRMA TRUpoint	7.80	7.77	7.83	11	4	18	422	362	482																		
<b>NOVA</b>																											
Electrolyte Systems	7.806	7.766	7.846							154	149	159	1.5	1.0	2.5	0.30	0.20	-0.40	124	119	129						
Stat Profile 1-5	7.806	7.766	7.846	10	6	14	427	367	487	151	146	156	1.4	0.9	1.9	0.30	0.20	-0.40	124	119	129						
<b>Osmetech</b>																											
Opti 1	ORL			ORL			ORL																				
Opti CCA	ORL			11	0	23	436	376	496	ORL			1.7	1.2	2.2	0.32	0.17	-0.47	121	116	126						
<b>Radiometer</b>																											
ABL 3, 30	7.826	7.786	7.866	10	6	14	392	332	452																		
ABL 300, 330	7.816	7.776	7.856	11	7	15	387	327	447																		
ABL 5	7.796	7.756	7.836	12	8	16	459	399	519																		
ABL, 50, 500, 520	7.806	7.766	7.846	10	6	14	397	337	457																		
ABL 505	7.806	7.766	7.846	10	6	14	397	337	457	148	143	153	1.3	0.8	1.8	0.32	0.22	-0.42									
ABL 600, 610, 620	7.806	7.766	7.846	10	6	14	397	337	457	148	143	153	1.3	0.8	1.8	0.32	0.22	-0.42	119	114	124	0	0	5	10.4	7.9	13.1
EML-100				0	0	0				148	143	153	1.3	0.8	1.8	0.33	0.23	-0.43	119	114	124						
ABL 70	7.79	7.74	7.84	11	4	18	475	415	535	145	140	150	0.8	0.3	1.3	0.43	0.28	-0.58									
ABL 77	7.79	7.74	7.84	11	4	18	475	415	535	145	140	150	0.8	0.3	1.3	0.43	0.28	-0.58	122	117	127	0	0	5			
ABL 700 Series**	7.803	7.763	7.843	10	6	14	397	337	457	148	143	153	1.3	0.8	1.8	0.33	0.23	-0.43	119	114	124	0	0	5	10.4	7.9	13.1
<b>i-STAT</b>																											
BG, E+	7.975	7.925	8.025	13	9	17	286	226	346	149	144	154	ORL			0.33	0.23	-0.43	119	114	124	ORL					
<b>Diamond</b>																											
proLYTE										148	143	153	1.5	1.0	2.5				125	119	131						
<b>Medica, iLyte, Menarini</b>																											
EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li										148	143	153	1.5	1.0	2.5				125	119	131						

\*Includes 840, 845, 850, 855, 860, 865 Analyzers

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

ORL - Outside (Analyzer's) Reportable Limits

Mission Diagnostics recognizes all trademarks and copyrights referenced herein.

### Manufacturer and Product Information

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

**Intended Use:** MISSION COMPLETE™ Linearity Control are assayed materials used for confirming the calibration and linearity of blood gas, electrolyte, and metabolite instruments for the analytes and analyzers listed on the Expected Values Chart.

**Product Description:** This control material is provided in five (5) distinct levels of pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, covering the significant range of the instrument performance. It is packaged in sealed glass ampoules, each containing 1.8 ml of solution. Ampoules are packaged in kits containing four (4) ampoules of each level.

**Active Ingredients:** MISSION COMPLETE™ is a buffered solution of electrolytes, glucose, and lactate. It has been equilibrated with specific levels of CO<sub>2</sub>, O<sub>2</sub>, and N<sub>2</sub>. This control contains no human or biological materials.

**For in vitro diagnostics use.**

### Directions for Use

The Linearity Control should be brought to a temperature of 20-25°C before use (see instructions regarding Expected Ranges). Allow at least four (4) hours for ampoules to equilibrate to this temperature prior to testing.

It is best to run calibration verification materials in the same manner as patient samples, however, please refer to the expected values chart enclosed and/or any specific instructions for your analyzer regarding the use of aqueous control materials. Follow the procedures listed below:

1. Perform a two-point calibration on your instrument before beginning the calibration verification procedure.
2. Beginning with level 1, hold the ampoule 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.
3. Open the ampule by snapping off the tip at the score. Use gauze, tissue, gloves, or an appropriate ampoule opener to protect fingers from cuts.
4. Immediately introduce the liquid from the ampule to the analyzer. Use direct aspiration, syringe transfer, or capillary mode techniques.
5. Record the results on the Data Collection and Linearity Worksheet provided for each analyte.
6. Repeat steps 2 through 5 for the remaining ampoules of level 1 until three (3) replicates are completed. (A fourth ampoule of each level is provided in case of accidental breakage or obvious sampling error.) Test levels 2, 3, 4, and 5 the same way. Record all values on the worksheets.
7. Calculate the mean value for each test analyte and compare your mean to the range on the Expected Values Chart. If your mean is within the range, circle "Y" at the question "OK?". If your mean is outside the range, circle "N" and take the corrective action.
8. To graph, the linearity of your results:
  - a. Using the graph area provided, plot the Test Value (mean) against the Expected Value.
  - b. Connect the plotted points to visualize linearity.

### Limitations

**Limitation:**

1. The Linearity 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 that would affect the testing of blood.
2. This product is intended for use 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:**

The expiration date stated on the Linearity Control packaging is for product stored at 2-8°C. The product may also be stored at room temperature (up to 25°C) for six (6) months, provided the labeled expiration date is not exceeded. Avoid exposure to freezing and temperatures greater than 30°C.

**Expected Ranges:**

The values for each analyte on the enclosed Expected Values Chart are based on multiple determinations performed on randomly selected samples from each lot. The listing for each instrument represents the expected range for ampoules that are at 25°C when tested. (Note: pO<sub>2</sub> values will vary inversely by about one percent (1%) per degree Celsius that the temperature of the ampoules varies from 25°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 acceptance criteria.

