

MISSION Trinity R CONTROL™
Blood Gas, Electrolyte, Metabolite, CO-Oximeter (Radiometer) Control

LOT: R8E132-EU
 Exp: 2010/04

Level 1
 PN: DD-97001D

Expected Ranges Chart

Blood Gas Analyzers	pH			pCO ₂ kPa			pO ₂ kPa			Na ⁺ mmol/L			K ⁺ mmol/L			Ca ⁺⁺ mmol/L			Cl ⁻ mmol/L			Glucose mg/dL			Lactate 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	Mean	Min	Max
Radiometer																														
ABL 3, 30	7.099	7.042	- 7.156	9.51	8.37	- 10.65	9.92	8.13	- 11.70																					
ABL 300, 330	7.099	7.042	- 7.156	9.51	8.37	- 10.65	9.92	8.13	- 11.70																					
ABL 5	7.085	7.028	- 7.141	10.36	9.11	- 11.60	9.24	7.58	- 10.90																					
ABL 50, 500, 510, 520	7.089	7.032	- 7.145	10.36	9.11	- 11.60	10.07	8.26	- 11.88																					
ABL 505	7.087	7.030	- 7.143	10.49	9.23	- 11.75	9.93	8.14	- 11.72	115	110	- 121	3.11	2.86	- 3.36	1.48	1.26	- 1.70	72	66	- 78									
ABL 555	7.085	7.028	- 7.141	10.22	8.99	- 11.45	9.38	7.69	- 11.07	115	110	- 121	3.11	2.86	- 3.36	1.52	1.29	- 1.75	72	66	- 78	38	32	- 44	6.3	5.2	- 7.4			
ABL 600, 605, 610, 615, 620, 625	7.089	7.032	- 7.145	10.36	9.11	- 11.60	10.07	8.26	- 11.88	115	110	- 121	3.11	2.86	- 3.36	1.50	1.28	- 1.73	72	66	- 78	38	32	- 44	6.3	5.1	- 7.4			
ABL 700,705,710,715,720,725,730,735	7.078	7.021	- 7.134	10.22	8.99	- 11.45	10.48	8.59	- 12.37	115	110	- 121	3.11	2.86	- 3.36	1.51	1.28	- 1.74	72	66	- 78	38	32	- 44	6.3	5.2	- 7.4			
ABL 805,810,815,820,825,830,835	7.082	7.025	- 7.138	10.22	8.99	- 11.45	10.89	8.93	- 12.86	115	110	- 121	3.11	2.86	- 3.36	1.52	1.29	- 1.75	72	66	- 78	38	32	- 44	6.3	5.2	- 7.4			
Ciba-Corning/Bayer																														
238	7.120	7.063	- 7.177	10.22	8.99	- 11.45	9.37	7.68	- 11.05																					
248	7.120	7.063	- 7.177	10.12	8.90	- 11.33	8.95	7.34	- 10.57																					
348	7.120	7.063	- 7.177	10.12	8.90	- 11.33	9.64	7.91	- 11.38																					
278	7.120	7.063	- 7.177	10.12	8.90	- 11.33	9.64	7.91	- 11.38																					
840, 850	7.123	7.066	- 7.180	10.52	9.26	- 11.78	9.78	8.02	- 11.54																					
IL																														
1304, 1306, 1312	7.110	7.053	- 7.167	9.58	8.43	- 10.73	7.61	6.24	- 8.98																					
BG3	7.110	7.053	- 7.167	9.98	8.78	- 11.18	7.75	6.35	- 9.14																					
BGE	7.110	7.053	- 7.167	10.12	8.90	- 11.33	7.61	6.24	- 8.98																					
AVL Scientific																														
945, 947	7.090	7.034	- 7.147	10.25	9.02	- 11.48	9.54	7.82	- 11.26																					
990, 995	7.090	7.034	- 7.147	10.25	9.02	- 11.48	9.27	7.60	- 10.93																					
Compact Series	7.090	7.034	- 7.147	10.25	9.02	- 11.48	9.27	7.60	- 10.93																					

CO-oximeters	tHb mmol/L			O ₂ Hb %			O ₂ Sat (sO ₂) %			COHb %			MetHb %			O ₂ Ct %			RHb (HHb) %		
	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
Radiometer																					
OSM3	4.61	6.4	- 8.4	34.2	34.1	- 39.1	36.9	36.8	- 41.8	2.3	0	- 6	3.0	1.8	- 3.8	3.8	2.3	- 5.3			
ABL 500, 510, 520	4.61	6.4	- 8.4	33.7	33.6	- 38.6	36.4	36.3	- 41.3	2.8	0.0	- 6.5	3.0	1.8	- 3.8				56	51	- 61
ABL 600, 605, 610, 615, 620, 625	4.61	6.4	- 8.4	33.7	33.6	- 38.6	36.4	36.3	- 41.3	2.8	0.0	- 6.5	2.8	1.8	- 3.8						

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 Trinity R™ Blood Gas, Electrolyte, Metabolite, CO-Oximeter Control is an assayed quality control material used for monitoring the performance of blood gas, electrolyte, metabolite, and CO-Oximeter (Radiometer) instrumentation for the analytes and analyzers listed on the Expected Values Chart.

Product Description: This control material is provided in three (3) distinct levels of pH, pCO₂, pO₂, Na⁺, K⁺, Cl⁻, Ca⁺⁺, glucose, lactate, tHb, O₂Hb, COHb, metHb & HHb covering the significant range of the instrument performance. It is packaged in sealed glass ampules, each containing 1.8 ml of solution.

Active Ingredients: MISSION Trinity R™ is a buffered solution of electrolytes, glucose, lactate and dyes. It has been equilibrated with specific levels of CO₂, O₂, and N₂. This control contains no human or biological 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**Limitations:**

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:

The expiration date stated on the Trinity R™ Control packaging is for product stored at 2-8°C. 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: pO₂ 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.

