

Mission Control™ Blood Gas and Electrolyte Control - Level 2

REF	DD-92002D	CE	IVD	2027/09	LOT	2410113
English						
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 1.8 ml of solution. Ampules are packed 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 ₂). It has been equilibrated with specific levels of CO ₂ , O ₂ , and N ₂ . This control contains no human-based materials.						
Directions for Use						
Immediately introduce the liquid from the ampule to the analyzer, following the instrument manufacturer's instructions for sampling a control material. Use direct aspiration, syringe transfer, or capillary mode techniques.						
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. (Normal pCO ₂ values will increase by 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.						
Lagerung:						
Bei 18-25°C aufbewahren. Vermeiden Sie Einfrörung und Aussetzung bei Temperaturen von mehr als 30°C. Diese Lagerung bei 4-25°C ist ohne negativer Auswirkung.						
Wertbereiche:						
Die Werte für jeden Kontrollanalyt auf der beiliegenden Wertbereichstabelle basieren auf mehreren Erhebungen, die von zufällig ausgewählten Proben jeder Packung gemacht wurden. Die Liste für jedes Instrument umfasst das erwartete Resultat für die jeweilige Ampulle bei der Prüfung bei 23°C. (Hinweis: pCO ₂ Werte variieren umgekehrt um einen Prozent (1%) pro Grad Celsius, da die Temperatur der Ampullen um 23°C variiert.)						
Die erwarteten Wertbereiche sollen als Leitfaden bei der Bewertung der Leistung von Analysegeräten dienen. Da die Instrumentausführung und Bedienungsbedingungen von Gerät zu Gerät jedes Labors seine eigenen Wertewartungen und Kontrollbeschränkungen erstellen. Der selbst erstellte Mitttwert sollte dem auf der vorgegebenen Wertbereichstabelle entsprechen.						
Temperature Limit						
Temperaturgrenze Limite de temperatura Limite de temperatura Limite de temperatura Temperaturgrenze 界限溫度 Границы температуры						
Consult Instructions for Use Gebräuchsanweisung beachten Consulez les instructions de usage Consulte as instruções de utilização Benutzen Sie die Anleitung für die Verwendung 参阅说明书使用 Проверьте инструкции по применению						
Lot Number Chargen-Nr. Número de lote Número de lote Número de lote Batchnummer 批次号 Номер серии						
Use by (YY-MM-DD) Verwendbar bis (JJJ-MM-TT) Date limite d'utilisation (JJ-JJ-JJ) Utar hasta el (AAAA-MM-DD) Utilizar até (AAAA-MM-DD) Anwend bar (YYYY-MM-DD) 效期至 (YYYY-MM-DD)						
Manufactured by Hersteller Fabricante Fabricante Fabricado por Representante autorizado Autorisiertes Repräsentant 授权代表 Санкционированное представительство						
Authorized Representative Bevollmächtigter Representante Representante Fremstellert af …制造 授权代表 Санкционированное представительство						
REF						
Catalog Number Katalog-Nr. Número de catálogo Número de catálogo Catalog 产品编号 Номер каталога						

IVD
For In Vitro Diagnostic Use
In vitro Diagnostic
Para Uso Diagnóstico in Vitro
Uit voor In Vitro Diagnose
对于体外诊断的使用
Для использования в диагностике in vitro

CE
European Conformity
CE-Konformitätszeichenung
Conformité Européenne
Conformidade com as normas europeias
Europäische overeenstemming
符合欧
Европейская Аккредитация

Temperature Limit
Temperaturlimit
Limite de temperatura
Limite de temperatura
Temperaturgrenze
界限溫度
Границы температуры

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Consulez les instructions de usage
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Authorized Representative
Bevollmächtigter
Representante
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Expected Ranges Chart

	pH			pCO ₂ mmHg			pO ₂ mmHg			Na ⁺ mmol/L			K ⁺ mmol/L			Ca ⁺⁺ mmol/L			Ca ⁺⁺ mg/dL			Cl ⁻ mmol/L			Li ⁺ mmol/L			tCO ₂ mmol/L														
Blood Gas/ISE Analyzer	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												
AADEE SA µGases	*7.400	*7.350	- *7.450	*38.0	*33.0	- *43.0	*115	*105	- *125	*136	*128	- *144	*4.21	*3.88	- *4.54	*1.13	*0.87	- *1.39	*4.52	*3.48	- *5.56	*91	*82	- *100																		
AADEE SA use																																										
AADEE SA RUMI BG	*7.40	*7.35	- *7.45	*37.5	*32.0	- *43.0	*116	*106	- *126	140	133	- 147	4.45	4.11	- 4.79	1.10	0.93	- 1.27	4.38	3.72	- 5.08	93	85	- 101																		
Caretium XI-921	8.10	8.01	- 8.19				130	123	- 137	4.03	3.69	- 4.37	1.14	0.97	- 1.31	4.56	3.88	- 5.24	93	85	- 101	1.02	0.89	- 1.15																		
CMD CMDLyte							133	126	- 140	4.32	3.98	- 4.66	1.18	1.01	- 1.35	4.71	4.04	- 5.40	92	84	- 100	1.06	0.93	- 1.19																		
CMD CMDLyte Plus							130	123	- 137	4.03	3.69	- 4.37	1.14	0.97	- 1.31	4.56	3.88	- 5.24	93	85	- 101	1.02	0.89	- 1.15																		
Corray Corlyte Analyzer							137	131	- 144	4.25	3.91	- 4.58	1.13	0.97	- 1.29	4.52	3.88	- 5.16	94	86	- 102	0.93	0.79	- 1.06																		
Comley AFT-400, 500 Series	7.27	7.21	- 7.33				139	132	- 146	4.50	4.16	- 4.84	1.09	0.92	- 1.26	4.38	3.68	- 5.04	100	91	- 108	1.05	0.92	- 1.18																		
Diamond CARELYTE							139	132	- 146	4.29	3.95	- 4.63	1.12	0.95	- 1.29	4.47	3.80	- 5.16	99	90	- 107	1.03	0.90	- 1.16																		
Diamond CARELYTE PLUS							132	124	- 139	4.22	3.78	- 4.66	*1.21	*1.05	- 1.39	*4.84	*4.20	- 5.56	92	84	- 100	1.12	0.98	- 1.25																		
Diamond PROLYTE							130	123	- 137	4.03	3.69	- 4.37	1.14	0.97	- 1.31	4.56	3.88	- 5.24	93	85	- 101	1.02	0.89	- 1.15																		
Diamond SMARTLYTE, GEMLYTE							133	126	- 140	4.32	3.98	- 4.66	1.18	1.01	- 1.35	4.71	4.04	- 5.40	92	84	- 100	1.06	0.93	- 1.19																		
Diamond SMARTLYTE PLUS							132	125	- 139	4.23	3.89	- 4.57							90	82	- 98																					
Diamond UNITY							152	137	- 167	4.48	4.09	- 4.87	1.11	0.99	- 1.23	4.42	3.96	- 4.92	109	97	- 121																					
Erba Mannheim, EC 90	7.420	7.361	- 7.479	31.1	25.2	- 37.0	153	135	- 171	144	137	- 151	4.36	4.02	- 4.69	1.12	0.96	- 1.29	4.50	3.84	- 5.16	102	94	- 110	1.06	0.92	- 1.19															
Eschweiler Combline	7.420	7.361	- 7.479	27.8	21.9	- 33.7	154	136	- 171	144	137	- 151	4.36	4.02	- 4.69	1.12	0.96	- 1.29	4.50	3.84	- 5.16	102	94	- 110	1.06	0.92	- 1.19															
Eschweiler Combisys II	7.420	7.361	- 7.479	27.8	21.9	- 33.7	154	136	- 171	142	135	- 149	4.36	4.02	- 4.69	1.12	0.96	- 1.29	4.50	3.84	- 5.16	102	94	- 110	1.06	0.92	- 1.19															
Eschweiler ECOLYTE							138	131	- 145	4.05	3.71	- 4.39	1.04	0.87	- 1.21	4.18	3.48	- 4.84																								
Fresenius Ionometer							133	126	- 140	4.32	3.98	- 4.66	1.18	1.01	- 1.35	4.71	4.04	- 5.40	92	84	- 100	1.06	0.93	- 1.19																		
Honiba Yumizen E100							145	138	- 152	4.43	4.09	- 4.77							99	90	- 107																					
IDEXX VetLyte							138	131	- 145	4.24	3.91	- 4.58	1.13	0.97	- 1.29	4.29	3.96	- 5.32	94	86	- 102	0.93	0.79	- 1.06																		
IL 1610, 1620	7.397	7.338	- 7.455	42.8	36.9	- 48.7	125	107	- 142																																	
IL 1630, 1640, 1650	7.397	7.338	- 7.455	42.8	36.9	- 48.7	123	106	- 140	140	133	- 147	3.91	3.60	- 4.22	1.07	0.91	- 1.24	4.28	3.64	- 4.96	98	90	- 106																		
IL BGE	7.397	7.338	- 7.455	42.8	36.9	- 48.7	123	106	- 140	138	131	- 144	3.91	3.60	- 4.22	1.07	0.91	- 1.24	4.28	3.64	- 4.96	98	90	- 106																		
IL Gem Premier, 3000	7.470	7.411	- 7.529	36.5	30.5	- 42.5	144	126	- 162	142	135	- 149	4.02	3.71	- 4.34	1.13	0.96	- 1.30	4.54	3.84	- 5.20																					
IL Gem Premier, 4000	7.460	7.401	- 7.519	36.5	30.5	- 42.5	148	130	- 166	138	131	- 145	4.42	4.11	- 4.74	1.16	0.99	- 1.33	4.66	3.96	- 5.32	97	89	- 106																		
IL I-Lyte	7.429	7.370	- 7.488				142	135	- 149	4.23	3.90	- 4.57	1.18	1.00	- 1.36	4.72	4.00	- 5.44	98	90	- 106	1.20	1.06	- 1.33																		
IL Synthesis 10, 15, 20, 25, 30, 35, 40, 45	7.397	7.338	- 7.455	38.8	33.3	- 44.2	130	111	- 148	140	133	- 147	3.87	3.57	- 4.18	1.07	0.91	- 1.24	4.28	3.64	- 4.96	98	90	- 107																		
InSight Electrolyte Analyzer							130	123	- 137	4.03	3.69	- 4.37	1.14	0.97	- 1.31	4.56	3.88	- 5.24	93	85	- 101	1.02	0.89	- 1.15																		
Intherma S-Lyte							130	123	- 137	4.03	3.69	- 4.37	1.14	0.97	- 1.31	4.56	3.88	- 5.24	93	85	- 101	1.02	0.89	- 1.15																		
ITC IRMA TRUpoint	7.42	7.36	- 7.48	42.4	36.5	- 48.3	133	114	- 152																																	
Max Ion	7.27	7.21	- 7.33				138	131	- 145	4.24	3.91	- 4.58	1.13	0.97	- 1.29	4.29	3.96	- 5.32	94	86	- 102	0.93	0.79	- 1.06																		
Medica EasyBloodGas	7.44	7.38	- 7.50	39.5	33.5	- 45.5	147	129	- 165																																	
Medica EasyElectrolytes							144	137	- 151	4.23	3.90	- 4.57																														
Medica EasyLyte NaK, Na/KCl, Na/KLi, Na/KCl/Cl, Na/K/pH/Ca	7.429	7.370	- 7.488				139	133	- 146	4.08	3.74	- 4.41	1.21	1.02	- 1.39	4.82	4.08	- 5.56	95	87	- 103	1.20	1.06	- 1.33																		
Medica EasyStat	7.44	7.38	- 7.50	39.5	33.5	- 45.5	151	133	- 169	140	133	- 147	3.92	3.62	- 4.22	0.99	0.83	- 1.14	3.98	3.32	- 4.56	93	85	- 101	1.24	1.11	- 1.37															
Medica ISE Module							145	138	- 152	4.23	3.90	- 4.57																														
MH Lab-ISE							130	123	- 137	4.03	3.69	- 4.37	1.14	0.97	- 1.30	4.56	3.88	- 5.20	93	85	- 101	1.02	0.89	- 1.15																		
MH Lab-ISE Plus							133	126	- 140	4.32	3.98	- 4.66	1.18	1.01	- 1.35	4.71	4.04	- 5.40	92	84	- 100	1.06	0.93	- 1.19																		
Nova Electrolyte Systems	7.407	7.348	- 7.457				142	135	- 149	4.25	3.92	- 4.59	0.98	0.82	- 1.13	3.92	3.28	- 4.52	101	93	- 110																					
Nova Stat Profile Systems	7.407	7.348	- 7.457	42.8	36.9	- 48.7	120	103	- 136	141	134	- 148	4.21	3.88	- 4.55	1.03	0.87	- 1.19	4.12	3.48	- 4.76	98	90	- 106																		
Nova pHox Series	7.455	7.430	- 7.480	33.4	28.3	- 38.4	140	134	- 146	139	135	- 143	4.21	3.88	- 4.55	1.03	0.87	- 1.19	4.12	3.48	- 4.76																					