

Mission Control™ Blood Gas and Electrolyte Control - Level 1

REF	DD-92001D	CE	IVD		2022/10	LOT	1911104
Intended Use:							
MISSION CONTROL™ Blood Gas and Electrolyte Control is an assayed quality control material intended for monitoring the measurements of pH+pO ₂ , pCO 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 ₃ 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 analyse 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: pO ₂ 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.							
Wertbereiche:							
Die Werte für jeden Kontrollansatz auf der beigelegten Wertbereichsliste basieren auf mehreren Ermittlungen, die von zufällig ausgewählten Proben jeder Partie stammen. Die Liste für jedes Instrument beschreibt das erwartete Resultat für die jeweilige Ampulle bei der Prüfung bei 23 °C. (Hinweis: pO ₂ Werte variieren umgekehrt um rund ein Prozent (1%) pro Grad C, da die Temperatur der Ampulle variiert um 23°C).							
Die erwarteten Wertbereiche sollen als Leitfäden bei der Bewertung der Leistung von Analysengeräten dienen. Da die Instrumentausführung und Betriebsbedingungen variieren können, sollte jedes Labor seine eigenen Wertewartungen und Kontrollbeschreibungen erstellen. Der selbst erstellte Mittiwert sollte dem auf der vorgegebenen Wertbereichsliste entsprechen.							
Lagerung:							
Bei 18-25 °C aufbewahren. Vermeiden Sie Einfrirung und Aussetzung bei Temperaturen von mehr als 30 °C. Die Lagerung bei 4-25 °C ist ohne negative Auswirkung.							
Grenzen präzise :							
Les valeurs pour chaque analyse de contrôle sur le diagramme de gammes inclus sont basées sur des déterminations multiples effectuées sur les échantillons sélectionnés aléatoirement choisis provenant de chaque lot. La liste pour chaque instrument représente la gamme prévue pour ces ampoules une fois examinée à 23°C. (Note: les valeurs pO2 changeront inversement par environ un pour cent (1%) degré C que la température des ampoules change de 23°C).							
Les gammes prévues sont fournies comme guide dans l'évaluation de performances d'analyseur. Comme la conception d'instrument et les conditions de fonctionnement peuvent changer, chaque laboratoire devrait établir ses propres valeurs et limites de commande. La valeur moyenne établie devrait faire partie des marges prévues montrées sur le diagramme.							
Temperature Limit							
Temperaturenlimit Limite de température Limite de temperatura Limite de temperatura Temperaturgrenze 溫标温湿度限制 溫标溫湿度限制 Температурные ограничения							
Consult Instructions for Use							
Begutachten Gebrauchsanweisung Consulter la notice d'emploi Consultar la instrucción de uso Consulte as instruções de utilização Bereit bringen 參照说明书使用 Рекомендации по применению							
Lot Number							
Chargen-Nr. Número de lote Número de lote Número de lote Batchnr. 批号 批次號 Номер серии							
Manufactured by							
Hergestellt von Fabricante por Fabricado por Fabricante autorizado Autorenser representant 製造 Санкционированный представитель							
EC REP							
Authorized Representative Bevollmächtigter Représentant agréé Representante autorizado Autorenser representant 授权的代表 санкционированный представитель							
REF							
Catalog Number Número de catálogo Número de catálogo Número de catálogo Catalog 产品编号 Номер каталога							

IVD
In Vitro Diagnostic Use
In Vitro Diagnostic
In Vitro
Uttar Aayna Em Diagnostic In Vitro
Il Vito diagnostic
仅供体外诊断使用
Для использования в диагностике в vitro

CE
European Conformity
CE-Konformitätszertifizierung
Conformité aux normes européennes
Conformación Europea
Conformidade com as normas europeias
Европейская сертификация
CE

Temperature Limit
Temperaturlimit
Limite de temperatura
Limite de temperatura
Temperaturgrenze
溫标温湿度限制
溫标溫湿度限制
Температурные ограничения

Consult Instructions for Use
Begutachten Gebrauchsanweisung
Consulter la notice d'emploi
Consultar la instrucción de uso
Consulte as instruções de utilização
Bereit bringen
參照说明书使用
Рекомендации по применению

Use by (YYYY-MM-DD)
Verwendbar bis (JJJJ-MM-TT)
Date de péremption (AAAA-MM-JJ)
Data de validade (AAAA-MM-DD)
Utilizar ate (AAAA-MM-DD)
Anwend für (AAAA-MM-DD)
效期到 (YYYY-MM-DD)
Пригодна до (ГГГГ-ММ-ДД)

Lot Number
Chargen-Nr.
Número de lote
Número de lote
Batchnr.
批号
批次號
Номер серии

Manufactured by
Hergestellt von
Fabricante por
Fabricado por
Fabricante autorizado
Autorenser representant
製造
Санкционированный представитель

Use by (YYYY-MM-DD)
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Authorized Representative
Bevollmächtigter
Représentant agréé
Representante autorizado
Autorenser representant
授权的代表
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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/SE 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	7.096	7.039	- 7.153	80.2	*70.5	- 89.9	104	*90.7	- *122	120	*109	- *126	2.23	*1.96	- *2.38	2.00	*1.74	- *2.26	8.00	*6.96	- *9.04	78	*71	*85							
AADEE SA µSE																															
AADEE SA RUMI BG	*7.13	*7.08	- *7.19	*78.5	*68.8	- *88.2	*97.3	*83.7	- *115.2	117	107	- 123	1.90	1.63	- 2.06	1.84	1.58	- 2.10	7.35	6.32	- 8.40	92	84	- 99							
Abbott i-Stat BG, E+	7.103	7.046	- 7.159	85.0	75.2	- 94.7	91.9	78.4	- 110	117	107	- 123	1.90	1.63	- 2.06	1.84	1.58	- 2.10	7.35	6.32	- 8.40	92	84	- 99							
Alere EPOC	7.103	7.046	- 7.159	85.0	75.2	- 94.7	91.9	78.4	- 110	117	107	- 123	1.90	1.63	- 2.06	1.84	1.58	- 2.10	7.35	6.32	- 8.40	92	84	- 99							
Convergent ISE/BG	7.09	7.03	- 7.14	77.1	67.1	- 87.1	91.6	80.6	- 107	114	103	- 120	1.93	1.65	- 2.09	1.99	1.66	- 2.32	7.95	6.64	- 9.28	83	76	- 90	0.24	0.20	- 0.28				
Cormay Corlyte Analyzer																															
Cornley AFT-400, 500 Series	6.96	6.91	- 7.02																												
Diamond CARELYTE																															
Diamond CARELYTE PLUS																															
Diamond PROLYTE																															
Diamond SMARTLYTE, GEMLYTE																															
Diamond SMARTLYTE PLUS																															
Diamond UNITY																															
Eschweiler Combiline	7.103	7.046	- 7.159	88.3	78.5	- 98.0	88.0	74.5	- 106	117	106	- 123	2.09	1.82	- 2.25	2.23	1.97	- 2.49	8.91	7.88	- 9.96	83	76	- 90	0.45	0.41	- 0.49				
Eschweiler Combisys II	7.106	7.049	- 7.162	83.3	73.5	- 93.0	90.0	76.5	- 108	117	106	- 123	2.09	1.82	- 2.25	2.23	1.97	- 2.49	8.91	7.88	- 9.96	85	78	- 92	0.45	0.41	- 0.49				
Eschweiler ECOLYTE																															
Eschweiler ECOSYS II	7.108	7.051	- 7.164	83.3	73.5	- 93.0	90.0	76.5	- 108	116	101	- 118	1.96	1.68	- 2.12	1.97	1.70	- 2.24	7.87	6.80	- 8.96										
Fresenius Ionometer																															
IDEXX Vetlyte																															
IL 1600 Series	7.103	7.046	- 7.159	87.0	77.0	- 96.9	77.9	66.9	- 93.3	118	107	- 124	1.90	1.63	- 2.06	1.81	1.55	- 2.06	7.23	6.20	- 8.24	89	82	- 96							
IL BGE	7.103	7.046	- 7.159	85.0	75.2	- 94.7	79.9	68.5	- 95.6	117	106	- 123	1.80	1.54	- 1.95	1.83	1.57	- 2.08	7.31	6.28	- 8.32	89	82	- 96							
IL Gen Premier, 3000	7.096	7.039	- 7.153	77.1	68.1	- 87.1	95.6	83.6	- 112	114	103	- 120	1.90	1.63	- 2.06	1.97	1.71	- 2.23	7.87	6.84	- 8.92										
IL Gen Premier, 4000	7.086	7.029	- 7.143	73.1	64.1	- 83.1	99.6	87.6	- 116	112	101	- 118	2.03	1.75	- 2.19	1.99	1.73	- 2.25	7.95	6.92	- 9.00	83	76	- 90							
IL Lyte	7.102	7.045	- 7.158							118	107	- 124	2.05	1.77	- 2.22	2.28	1.95	- 2.60	9.11	7.80	- 10.40	86	79	- 93	0.24	0.21	- 0.28				
IL Synthesis 10, 15, 20, 25, 30, 35, 40, 45	7.103	7.046	- 7.159	81.5	72.2	- 90.8	80.0	68.6	- 95.8	118	107	- 124	1.87	1.60	- 2.02	1.85	1.60	- 2.10	7.39	6.40	- 8.40	89	82	- 96							
InSight Electrolyte Analyzer										111	100	- 117	1.96	1.68	- 2.12	2.13	1.86	- 2.40	8.52	7.44	- 9.60	77	71	- 83	0.29	0.25	- 0.33				
Intherma S-Lyte										111	100	- 117	1.96	1.68	- 2.12	2.13	1.86	- 2.40	8.52	7.44	- 9.60	77	71	- 83	0.29	0.25	- 0.33				
ITC IRMA TRUpoint	7.12	7.06	- 7.17	84.9	75.2	- 94.6	86.8	74.2	- 104																						
Max Ion	7.01	6.96	- 7.07							115	104	- 121	2.11	1.84	- 2.26	2.52	2.26	- 2.78	10.08	9.04	- 11.12	78	71	- 85	0.27	0.23	- 0.31				
Medica EasyBloodGas	7.09	7.03	- 7.14	79.1	69.1	- 89.1	89.6	78.6	- 105																						
Medica EasyElectrolytes										118	107	- 124	2.05	1.76	- 2.22	2.28	1.95	- 2.60	9.11	7.80	- 10.40	83	76	- 89	0.23	0.20	- 0.27				
Medica EasyLyte Na/K, Na/KCl, Na/K/Li, Na/K/Cl/Li, Na/K/pH/Ca	7.102	7.045	- 7.158							113	103	- 119	2.06	1.77	- 2.23	2.28	1.95	- 2.60	9.11	7.80	- 10.40	83	76	- 89	0.24	0.21	- 0.28				
Medica EasyStat	7.09	7.03	- 7.14	77.1	67.1	- 87.1	91.6	80.6	- 107	114	103	- 120	1.93	1.65	- 2.09	1.99	1.66	- 2.32	7.95	6.64	- 9.28	80	73	- 87	0.03	0.03	0.03				
Medica ISE Module										120	109	- 126	2.15	1.86	- 2.32	2.28	1.95	- 2.60	9.11	7.80	- 10.40	86	79	- 92	0.25	0.22	- 0.29				
MH Lab-ISE										111	100	- 117	1.96	1.68	- 2.12	2.13	1.86	- 2.40	8.52	7.44	- 9.60	77	71	- 83	0.29	0.25	- 0.33				
Nova Electrolyte Systems	7.123	7.065	- 7.180							118	107	- 124	2.10	1.81	- 2.27	2.40	2.05	- 2.74	9.59	8.20	- 10.96	91	83	- 98	0.26	0.22	- 0.29	28.2	24.2	- 32.2	
Nova Stat Profile Systems	7.133	7.075	- 7.190	84.0	74.4	- 93.6	82.9	71.0	- 99.2	117	107	- 123	2.00	1.72	- 2.16	1.86	1.60	- 2.12	7.43	6.40	- 8.48	86	79	- 92							
Nova pHox Series	7.140	7.082	- 7.197	84.9	75.2	- 94.6	88.8	75.8	- 106	117	107	- 123	2.00	1.72	- 2.16	1.86	1.60	- 2.12	7.43	6.40	- 8.48	86	79	- 92							
OptiMedical Opti 1	7.14	7.08	- 7.19	84.9	75.2	- 94.6	88.8	75.8	- 106																						
OptiMedical Opti CCA	7.14	7.08	- 7.19	84.9	75.2	- 94.6	105.4	91.9	- 123	114	103	- 119	1.78	1.51	- 1.93	1.85	1.59	- 2.11	7.39	6.36	- 8.44	81	75	- 88							
OptiMedical LION	7.10	7.03	- 7.16							102	94	- 104	1.40	1.23	- 1.45	1.84	1.57	- 2.10	7.35	6.28	- 8.40	84	77	- 92							
OptiMedical R	7.14	7.08	- 7.19	85.9	75.8	- 95.9	98.9	85.7	- 116	111	100	- 116	1.30	1.03	- 1.45	1.80	1.53	- 2.06	7.19	6.12	- 8.24										
PT Diatron DPLyte										111	100	- 117	1.96	1.68	- 2.12	2.13	1.86	- 2.40	8.52	7.44	- 9.60	77	71	- 83	0.25	0.21	- 0.29				
Radiometer ABL 5	7.12	7.06	- 7.18	72.6	64.6	- 80.6	91.6	79.6	- 107.9																						
Radiometer ABL 50, 500, 505, 510, 520	7.094	7.037	- 7.151	81.4	72.4	- 90.4	97.9	84.9	- 115	117	106	- 123	1.78	1.51	- 1.94	2.00	1.71	- 2.28	7.99	6.84	- 9.12										
Radiometer ABL 55	7.112	7.055	- 7.16																												