

Stat Profile Prime Plus® Blood Gas, CO-Oximeter, Chemistry Controls Auto-Cartridge with Creatinine

Cartucho automático con creatinina para controles de química, gases en sangre y cooxímetro Stat Profile Prime Plus®, Cartouche automatique de contrôles de gaz du sang/CO-oxymètre, chimie Stat Profile Prime Plus® avec créatine, Stat Profile Prime Plus® Auto-Kassette mit Kreatinin für Blutgas-, CO-Oximeter- und Blutchemiekontrollen, Αυτόματο φυσιγγίο υλικού ελέγχου χημείας ασπίνων αίματος, CO-Οξύμετρο Stat Profile Prime Plus®, Cartuccia con creatinina per controlli automatici chimici per gas ematici/CO-ossimetría Stat Profile Prime Plus®, Cartucho automático de controles de química, de CO-oxímetro e de Gás no sangue Stat Profile Prime Plus® com creatinina, Stat Profile Prime Plus® vérág, CO-oximéter, kémiai kontrollok automatikus patron kreatininnel, Stat Profile Prime Plus® Co-Oximeter, Stat Profile Prime Plus® 血液ガス, CO オキシメーター、生化学検査用コントロール自動カートリッジ(クレアチニン), 코레이티너 사용 Stat Profile Prime Plus® 혈액 가스, CO-산소 농도계, 화학 조절제 자동 카트리지, Stat Profile Prime Plus® 血气、一氧化碳血氧仪、化学对照溶液自动试剂盒(含肌酐)

ロール自動カートリッジ(クレアチニン), 코레이티너 사용 Stat Profile Prime Plus® 혈액 가스, CO-산소 농도계, 화학 조절제 자동 카트리지, Stat Profile Prime Plus® 血气、一氧化碳血氧仪、化学对照溶液自动试剂盒(含肌酐)

LOT 24117039
2025-10-17

CONTROL 1 2 3 4 5

Expected Ranges, Rangos esperados, Plages attendues, Erwartungsbereiche, Αναμενόμενο εύρος, Intervalli previsti, Intervalos previstos, Várt tartományok, הטווחים הצפויים, 予測範囲, 예상 범위, 预期范围值

		CONTROL 1	CONTROL 2	CONTROL 3	CONTROL 4	CONTROL 5
		min - \bar{x} - max				
pH		7.207 - 7.237 - 7.267	7.401 - 7.431 - 7.461	7.601 - 7.631 - 7.661		
H ⁺	nmol/L	62 - 58 - 54	40 - 37 - 35	25 - 23 - 22		
PCO ₂	mmHg	46.4 - 53.4 - 60.4	34.4 - 39.4 - 44.4	17.4 - 21.4 - 25.4		
PCO ₂	kPa	6.2 - 7.1 - 8.0	4.6 - 5.2 - 5.9	2.3 - 2.8 - 3.4		
PO ₂	mmHg	50.5 - 60.5 - 70.5	92.8 - 102.8 - 112.8	131.6 - 146.6 - 161.6		
PO ₂	kPa	6.7 - 8.0 - 9.4	12.3 - 13.7 - 15.0	17.5 - 19.5 - 21.5		
SO ₂	%	46 - 49 - 52	76 - 79 - 82	88 - 91 - 94		
Hct	%	57 - 60 - 63	36 - 39 - 42	22 - 25 - 28		
Na ⁺	mmol/L			139.3 - 143.3 - 147.3	111.2 - 115.2 - 119.2	
K ⁺	mmol/L			3.73 - 3.98 - 4.23	5.89 - 6.19 - 6.49	
Cl ⁻	mmol/L			123.4 - 127.9 - 132.4	93.4 - 97.9 - 102.4	
iCa	mmol/L			1.00 - 1.08 - 1.16	1.36 - 1.48 - 1.60	
iCa	mg/dL			4.0 - 4.3 - 4.6	5.5 - 5.9 - 6.4	
iMg	mmol/L			0.59 - 0.66 - 0.73	1.07 - 1.22 - 1.37	
iMg	mg/dL			1.4 - 1.6 - 1.8	2.6 - 3.0 - 3.3	
Glu	mg/dL			73 - 81 - 89	245 - 270 - 295	
Glu	mmol/L			4.1 - 4.5 - 4.9	13.6 - 15.0 - 16.4	
Lac	mmol/L			1.7 - 2.0 - 2.3	6.2 - 6.9 - 7.6	
Lac	mg/dL			15.1 - 17.8 - 20.5	55.2 - 61.5 - 67.7	
BUN	mg/dL			13 - 18 - 23	42 - 52 - 62	
BUN	mmol/L			4.6 - 6.4 - 8.2	15.0 - 18.6 - 22.1	
Urea	mg/dL			27.9 - 38.6 - 49.3	90.1 - 111.5 - 133.0	
Urea	mmol/L			4.6 - 6.4 - 8.2	15.0 - 18.6 - 22.1	
Creatinine	mg/dL			0.60 - 0.90 - 1.20	5.60 - 6.60 - 7.60	
Creatinine	mmol/L			0.05 - 0.08 - 0.11	0.50 - 0.58 - 0.67	
Creatinine	μmol/L			50 - 60 - 110	500 - 580 - 670	
HbF*	%	79.0 - 87.0 - 95.0	37.2 - 52.2 - 67.2	17.6 - 22.6 - 27.6		
tHb	g/dL	18.8 - 20.6 - 22.4	12.9 - 14.4 - 15.9	5.8 - 6.8 - 7.8		
tHb	g/L	188 - 206 - 224	129 - 144 - 159	58 - 68 - 78		
tHb	mmol/L	11.7 - 12.8 - 13.9	8.0 - 8.9 - 9.9	3.6 - 4.2 - 4.8		
O ₂ Hb	%	19.4 - 21.9 - 24.4	44.8 - 48.8 - 52.8	75.8 - 80.8 - 85.8		
COHb	%	24.7 - 28.7 - 32.7	16.5 - 20.5 - 24.5	2.2 - 6.2 - 10.2		
MetHb	%	24.3 - 27.3 - 30.3	15.0 - 18.0 - 21.0	2.2 - 5.2 - 8.2		
HbO	%	18.2 - 22.2 - 26.2	8.7 - 12.7 - 16.7	3.8 - 7.8 - 11.8		
tBil*	mg/dL	17.9 - 21.9 - 25.9	9.6 - 11.6 - 13.6	5.7 - 6.1 - 6.5		
tBil*	μmol/L	306.1 - 374.5 - 442.9	164.2 - 198.4 - 232.6	97.5 - 104.3 - 111.2		
tBil*	mg/L	179.0 - 219.0 - 259.0	96.0 - 116.0 - 136.0	57.0 - 61.0 - 65.0		

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Product Description
Aqueous quality control material for monitoring the performance of pH, PO₂, PO₃, bicarbonate (HCO₃), total hemoglobin (Ht), total hematocrit (Hct), methemoglobin (MetHb), carboxyhemoglobin (COHb), metahemoglobin (MetHb) and deoxyhemoglobin (DyHb) in Levels 1, 2 and 3 as well as Na⁺, K⁺, Cl⁻, Ca²⁺, Mg²⁺, glucose, lactate, BUN (urea), creatinine and iCa in Levels 4 and 5. A charge kit consisting of 2 syringes filled with creatinine solution is included for cartridge activation prior to installation. For use with the Stat Profile Prime Plus Analyzer ONLY.

Intended Use
Intended for *in vitro* diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime Plus Analyzer.

Methodology
Refer to Stat Profile Prime Plus Analyzer Instructions For Use Manual for Methodology and Principles.

Composition
Control Levels 1, 2 and 3 are buffered bipartite solutions containing dextrose, salts and preservatives. Each level has a known pH and contains a known O₂, CO₂ and Na⁺ value. Control Levels 4 and 5 are buffered solutions containing known concentrations of Na⁺, K⁺, Cl⁻, Ca²⁺, Mg²⁺, glucose, lactate, BUN (urea), creatinine and preservatives. Each pouch contains a minimum of 100 mL. Controls contain no substances of human origin, however good laboratory practices should be followed during handling of these materials. DO NOT FREEZE.

Warnings and Cautions
DO NOT FREEZE. Mix the cartridge by gently inverting for several seconds. DO NOT SHAKE CARTRIDGE. Refer to Stat Profile Prime Plus Analyzer Instructions for Use Manual for complete information.

Intended for *in vitro* diagnostic use. Follow standard practices for handling for laboratory reagents.

Storage
Store at 2-8°C (35-47°F). DO NOT FREEZE.

Directions for Use
Ensure cartridge is at room temperature prior to installation.

Level 4 and Level 5 must be charged with creatinine syringes prior to installation of the Control Cartridge. The 2 syringes are labeled and coded to correspond with the syringes on the cartridge.

Activation steps as follows:

1. Hold the syringe with tip down and remove needle.

2. Attach one of the two creatinine syringes to the cartridge. Remove the protective cover from the needle.

3. Slowly depress syringe plunger until the contents are dispensed. DO NOT PULL BACK ON THE PLUNGER TO FLUSH CONTENTS OUT OF THE SYRINGE.

4. Remove the protective cover from the other syringe and insert it firmly into the cartridge.

5. Repeat Steps 1-4 for the remaining control.

6. After all activation steps are completed, the cartridge is ready for use.

Verify that the lot Number on the Expected Ranges Table corresponds to the Lot Number on the cartridge. Refer to Stat Profile Prime Plus Analyzer Instructions for Use Manual for complete directions.

Limitations
PO₂ values are relatively inversely proportional to temperature (approximately 1% /°C²). Therefore, it is critical to follow the temperature guidelines described in "Directions for Use." The Expected Range values are specific for instruments and controls manufactured by Nova Biomedical. Once installed, each Stat Profile Prime Plus cartridge may be used for a maximum of 21 days from the initial installation date. After which time the system will indicate the cartridge is invalid. Each cartridge may be inserted and removed from the analyzer a maximum of 8 times.

Repeatability
Repeatability is ± 1% for the expected ranges.

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