

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 Blutgases-, CO-Oximeter- und Blutchemiekontrollen, Αυτόματο φυσίγγιο υλικού ελέγχου χρησίας αερίων αίματος, CO-Οξύμετρο Stat Profile Prime Plus®, Cartuccia con creatinina per controlli automatici chimici per gas ematici/CO-ossimetria 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® vérágz, CO-oximéter, kémiai kontrollok automatikus patron kreatininnel, Stat Profile Prime Plus® Co-Oximeter צג גז, 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(クリアチニン), 크레아티닌 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(クリアチニン), クレアチニン 使用 Stat Profile Prime Plus® 血气、CO-血氧仪、化学对照溶液自动试剂盒(含肌酐)

LOT

24169134



2025-11-29

CONTROL 1 2 3 4 5

Expected Ranges, Rangos esperados, Plages attendues, Erwartungsbereiche, Αναμενόμενο εύρος, Intervalli previsti, Intervalos previstos, Várt tartományok, הטרוּתִים הַצְפִּיִּים, 預測範圍, 예상 범위, 预期范围值

		CONTROL 1 min - \bar{x} - max	CONTROL 2 min - \bar{x} - max	CONTROL 3 min - \bar{x} - max	CONTROL 4 min - \bar{x} - max	CONTROL 5 min - \bar{x} - max
pH		7.212 - 7.242 - 7.272	7.393 - 7.423 - 7.453	7.607 - 7.637 - 7.667		
H ⁺	nmol/L	61 - 57 - 53	40 - 38 - 35	25 - 23 - 22		
PCO ₂	mmHg	45.5 - 52.5 - 59.5	35.4 - 40.4 - 45.4	17.0 - 21.0 - 25.0		
PCO ₂	kPa	6.1 - 7.0 - 7.9	4.7 - 5.4 - 6.0	2.3 - 2.8 - 3.3		
PO ₂	mmHg	54.1 - 64.1 - 74.1	99.8 - 109.8 - 119.8	133.6 - 148.6 - 163.6		
PO ₂	kPa	7.2 - 8.5 - 9.9	13.3 - 14.6 - 15.9	17.8 - 19.8 - 21.8		
SO ₂	%	47 - 50 - 53	77 - 80 - 83	88 - 91 - 94		
Hct	%	56 - 59 - 62	36 - 39 - 42	21 - 24 - 27		
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 - 80 - 110	500 - 580 - 670	
HbF*	%	79.0 - 87.0 - 95.0	38.3 - 53.3 - 68.3	18.7 - 23.7 - 28.7		
tHb	g/dL	19.1 - 20.9 - 22.7	13.1 - 14.6 - 16.1	5.9 - 6.9 - 7.9		
tHb	g/L	191 - 209 - 227	131 - 146 - 161	59 - 69 - 79		
tHb	mmol/L	11.9 - 13.0 - 14.1	8.1 - 9.1 - 10.0	3.7 - 4.3 - 4.9		
O ₂ Hb	%	21.3 - 23.8 - 26.3	45.1 - 49.1 - 53.1	75.8 - 80.8 - 85.8		
COHb	%	24.5 - 28.5 - 32.5	16.2 - 20.2 - 24.2	2.1 - 6.1 - 10.1		
MetHb	%	24.4 - 27.4 - 30.4	15.2 - 18.2 - 21.2	2.4 - 5.4 - 8.4		
HHb	%	18.1 - 22.1 - 26.1	8.5 - 12.5 - 16.5	3.7 - 7.7 - 11.7		
IBI*	mg/dL	17.8 - 21.8 - 25.8	9.5 - 11.5 - 13.5	5.7 - 6.1 - 6.5		
IBI*	μmol/L	304.4 - 372.8 - 441.2	162.5 - 196.7 - 230.9	97.5 - 104.3 - 111.2		
IBI*	mg/L	178.0 - 218.0 - 258.0	95.0 - 115.0 - 135.0	57.0 - 61.0 - 65.0		

EN

ES

FR

Product Description

Aqueous control material for monitoring the performance of pH, PCO₂, PO₂, SO₂, hematocrit (Hct), fetal hemoglobin (HbF), total hemoglobin (Hb), total bilirubin (TBil), oxyhemoglobin (O₂Hb), carboxyhemoglobin (COHb), methemoglobin (MetHb), and deoxyhemoglobin (DyHb) in blood samples, as well as Na⁺, K⁺, Cl⁻, Ca²⁺, Mg²⁺, Glucose, Lactate, BUN (urea), and Creatinine in Level 4 and 5, a cartridge consisting of 2 syringes filled with creatinine solution is included for reagent activation prior to installation. For use with Stat Profile Prime Plus Analyzers.

Intended Use

In-vitro diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime Plus Analyzers.

Methodology

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

Components

Controls Levels 1, 2 and 3 are buffered bicarbonate solutions containing dye and preservatives. Each level has a known pH and deoxyhemoglobin (DyHb) and known Na⁺, CO₂ and N₂ levels. Control Level 4 and 5 are buffered solutions containing known concentrations of Na⁺, K⁺, Cl⁻, Ca²⁺, Mg²⁺, glucose, lactate, BUN (urea), and creatinine. Each pouch contains a minimum of 100 mL. Controls contain no constituents of human origin; however good laboratory practices should be followed during handling of these materials. (REF. NCCLS DOCUMENT M29-T2*)

Warnings and Cautions

DO NOT SHAKE. Do not let 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 laboratory reagents.

Storage

Store at 2-8°C (37-46°F). DO NOT FREEZE.

Directions for use

Ensure controls are at ambient temperature prior to installation.

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

1. Hold the cartridge by the handle and remove protective cap.

2. Attach one of the enclosed needles to the syringes. Remove the protective cover from the needle.

3. Insert the needle and attach the syringe to the appropriate fitting on the cartridge.

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

5. Remove the needle from the fitting and discard in an appropriate sharps container.

6. Repeat Steps 1-5 for the next Control.

7. Mix cartridge well by gently inverting for 1 minute. Cartridge is ready for use.

Very carefully remove the protective cap. Expose the cartridge to the light to activate the dye in the cartridge. Refer to Stat Profile Prime Plus Analyzer Instructions for Use Manual for complete directions.

Limitations

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