



CERTIFICATE OF ANALYSIS

Stat Profile pHox Plus L Calibrator Cartridge D
Lot Number 25134052

Ref Number 34088
Exp Date 2026-11-01
Date of Manufacture 2025-05-01
UDI# (01)00385480340885(11)250501(17)261101(10)25134052

Cal-A L/N 25121072			Cal-B L/N 25121073			Cal-C L/N 25121074		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
Na mmol/L	142 - 144	Pass	HCO3 mmol/L	45.90 - 47.78	Pass	pH @ 37C	7.332 - 7.338	Pass
HCO3 mmol/L	24.42 - 25.42	Pass				Ca mmol/L	2.01 - 2.07	Pass
K mmol/L	4.03 - 4.09	Pass				Na mmol/L	72.5 - 73.5	Pass
Cl mmol/L	97.2 - 98.8	Pass				K mmol/L	10.04 - 10.20	Pass
Ca mmol/L	1.01 - 1.03	Pass				Cl mmol/L	52.6 - 53.4	Pass
Glu mg/dL	39.6 - 40.4	Pass				Glu mg/dL	198 - 202	Pass
Lac mmol/L	0.8 - 1.2	Pass				Lac mmol/L	5.5 - 6.5	Pass
Cal-D L/N 25121075			Reference L/N 25121045					
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>			
pH @ 37C	6.788 - 6.794	Pass	KCl mol/L	1.8 - 2.2	Pass			
Glu mg/dL	990 - 1010	Pass						
Lac mmol/L	10.5 - 13.5	Pass						

This certifies that this product was manufactured and tested at Nova Biomedica-Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical-Devices Quality Management Systems Requirements, Medical-Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Awishi-M

Approval

QC Inspector
Title

12/10/2025
Date