



CERTIFICATE OF ANALYSIS

Stat Profile pHox Plus M Calibrator Cartridge C
Lot Number 25161025

Ref Number 45146
Exp Date 2026-11-28
Date of Manufacture 2025-05-28
UDI# (01)00385480451468(11)250528(17)261128(10)25161025

Cal-A L/N 25148088			Cal-B L/N 25148089			Cal-C L/N 25148005		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
Na mmol/L	136 - 138	Pass	HCO3 mmol/L	42.24 - 43.96	Pass	pH @ 37C	7.332 - 7.338	Pass
HCO3 mmol/L	21.07 - 21.93	Pass				Ca mmol/L	1.97 - 2.03	Pass
K mmol/L	3.97 - 4.03	Pass				Na mmol/L	70.5 - 71.5	Pass
Mg mmol/L	0.49 - 0.51	Pass				K mmol/L	9.92 - 10.08	Pass
Ca mmol/L	0.99 - 1.01	Pass				Cl mmol/L	1.38 - 1.42	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 25148006			Reference L/N 25148090					
	<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

Auishi-M

Approval

QC Inspector

Title

1/28/2026

Date