



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1
Lot Number 24110053

Ref Number 48834
Exp Date 2025-10-04

Date of Manufacture 2024-04-04

UDI# (01)00385480488341(11)240404(17)251004(10)24110053

Table with 3 columns: Cal-A L/N, Spec, Pass/Fail. Rows include pH @ 37C and Lac mmol/L.

Table with 3 columns: Cal-B L/N, Spec, Pass/Fail. Rows include pH @ 37C, Na mmol/L, K mmol/L, Cl mmol/L, Ca mmol/L, and Mg mmol/L.

Table with 3 columns: Cal-C L/N, Spec, Pass/Fail. Rows include Na mmol/L, K mmol/L, Cl mmol/L, Ca mmol/L, Mg mmol/L, Glu mg/dL, Lac mmol/L, BUN mg/dL, and HCO3 mmol/L.

Table with 3 columns: Cal-D L/N, Spec, Pass/Fail. Rows include Glu mg/dL, Lac mmol/L, BUN mg/dL, and HCO3 mmol/L.

Table with 3 columns: Flush L/N, Spec, Pass/Fail. Rows include Aqueous, Salt, and Solution.

Table with 3 columns: Reference L/N, Spec, Pass/Fail. Row includes KCl mol/L.

This certifies that this product was manufactured and tested at Nova BiomedCal-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

4/30/2024

Date