



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1
Lot Number 23275057

Ref Number 48834
Exp Date 2025-03-13

Date of Manufacture 2023-09-13

UDI# (01)00385480488341(11)230913(17)250313(10)23275057

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include pH @ 37C and Lac mmol/L for Cal-A L/N 23261012.

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include pH @ 37C, Na mmol/L, K mmol/L, Cl mmol/L, Ca mmol/L, and Mg mmol/L for Cal-B L/N 23257049.

Table with 3 columns: Analyte, 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 for Cal-C L/N 23257050.

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include Glu mg/dL, Lac mmol/L, BUN mg/dL, and HCO3 mmol/L for Cal-D L/N 23257051.

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include Aqueous, Salt, and Solution for Flush L/N 23262076.

Table with 3 columns: Analyte, Spec, Pass/Fail. Row includes KCl mol/L for Reference L/N 23256058.

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

10/6/2023

Date