



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1
Lot Number 24235060

Ref Number 48834
Exp Date 2026-02-07

Date of Manufacture 2024-08-07

UDI# (01)00385480488341(11)240807(17)260207(10)24235060

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include pH @ 37C and Lac mmol/L for Cal-A L/N 24222090.

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 24220060.

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 24220061.

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 24220062.

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include Aqueous, Salt, and Solution for Flush L/N 24227025.

Table with 3 columns: Analyte, Spec, Pass/Fail. Row includes KCl mol/L for Reference L/N 24221052.

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

Handwritten signature of Romanus Aichta

Approval

QC Inspector

Title

8/29/2024

Date