



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1
Lot Number 24178026

Ref Number 48834
Exp Date 2025-12-13

Date of Manufacture 2024-06-13

UDI# (01)00385480488341(11)240613(17)251213(10)24178026

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include pH @ 37C and Lac mmol/L for Cal-A L/N 24165057.

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 24165058.

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 24165069.

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 24165070.

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include Aqueous, Salt, and Solution for Flush L/N 24170008.

Table with 3 columns: Analyte, Spec, Pass/Fail. Row includes KCl mol/L for Reference L/N 24165014.

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

Haneen Aldarwish

Approval

QC Inspector
Title

7/8/2024
Date