



CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1
Lot Number 23202056

Ref Number 48834
Exp Date 2024-12-14

Date of Manufacture 2023-06-14

UDI# (01)00385480488341(11)230614(17)241214(10)23202056

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include pH @ 37C and Lac mmol/L for Cal-A L/N 23165055.

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 23165057.

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 23165058.

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 23165059.

Table with 3 columns: Analyte, Spec, Pass/Fail. Rows include Aqueous, Salt, and Solution for Flush L/N 23165060.

Table with 3 columns: Analyte, Spec, Pass/Fail. Row includes KCl mol/L for Reference L/N 23165017.

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

Haneen Aldarwish

Approval

QC Inspector

Title

7/28/2023

Date