



CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Cal Cartridge 1 w/Creat
Lot Number 24120066

Ref Number 48836
Exp Date 2025-10-19
Date of Manufacture 2024-04-19

UDI# (01)00385480488365(11)240419(17)251019(10)24120066

Cal A L/N 24113019

Cal B L/N 24110042

Cal C L/N 24110043

Table with 3 columns: Spec, Pass/Fail. Rows: pH @ 37C, Lac mmol/L.

Table with 3 columns: Spec, Pass/Fail. Rows: pH @ 37C, Na mmol/L, K mmol/L, Cl mmol/L, Ca mmol/L, Mg mmol/L.

Table with 3 columns: Spec, Pass/Fail. Rows: Na mmol/L, K mmol/L, Cl mmol/L, BUN mg/dl, Glu mg/dl, Lac mmol/L, Ca mmol/L, Mg mmol/L, Creat mg/dl, HCO3 mmol/L.

Cal D L/N 24110044

Flush L/N 24115064

Reference L/N 24110024

Table with 3 columns: Spec, Pass/Fail. Rows: BUN mg/dl, Glu mg/dl, Lac mmol/L, Creat mg/dl, CO3 mmol/L.

Table with 3 columns: Spec, Result. Row: Aqueous Salt Solution.

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

This certifies that this product was manufactured and tested at Nova Biomedical 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

5/17/2024

Date