




CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Cal Cartridge 1
Lot Number 16356063

Ref Number 48834
Exp Date 2017-12-08
Date of Manufacture 2016-12-08

| | | | | | | | | |
|-------------|-------------|-----------|--------------|-------------|-----------|-------------|-------------|-----------|
| Cal A | L/N | 16354014 | Cal B | L/N | 16349054 | Cal C | L/N | 16354015 |
| | Spec | Pass/Fail | | Spec | Pass/Fail | | Spec | Pass/Fail |
| pH @ 37C | 7.351-7.357 | Pass | pH @ 37C | 6.822-6.828 | Pass | Na mmol/L | 139.0-141.0 | Pass |
| Lac mmol/L | 13.5-16.5 | Pass | Na mmol/L | 69.5-70.5 | Pass | K mmol/L | 3.97-4.03 | Pass |
| | | | K mmol/L | 9.9-10.1 | Pass | Cl mmol/L | 118.0-120.0 | Pass |
| | | | Cl mmol/L | 39.7-40.3 | Pass | BUN mg/dl | 9.9-10.1 | Pass |
| | | | Ca mmol/L | 1.97-2.03 | Pass | Glu mg/dl | 78.8-81.2 | Pass |
| | | | Mg mmol/L | 1.48-1.52 | Pass | Lac mmol/L | 1.8-2.2 | Pass |
| | | | | | | Ca mmol/L | 0.98-1.02 | Pass |
| | | | | | | Mg mmol/L | 0.49-0.51 | Pass |
| | | | | | | HCO3 mmol/L | 18.43-19.19 | Pass |
| Cal D | L/N | 16354010 | Flush | L/N | 16349042 | Reference | L/N | 16343019 |
| | Spec | Pass/Fail | | Spec | Result | | Spec | Pass/Fail |
| BUN mg/dl | 49.4-50.6 | Pass | Aqueous Salt | N/A | Present | KCl mol/L | 1.8-2.2 | Pass |
| Glu mg/dl | 197-203 | Pass | Solution | | | | | |
| Lac mmol/L | 5.5-6.5 | Pass | | | | | | |
| HCO3 mmol/L | 37.05-38.57 | Pass | | | | | | |

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CFR-Part 820, Quality System Regulation (QSR), Current Good Manufacturing Practice (cGMP) and EN ISO 13485:2012, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.


Approval

QC Supervisor
Title

2/8/2017
Date