



CERTIFICATE OF ANALYSIS

STP pHoxUltra/CCX CO-Oximeter Cal Cartridge
w/Bilirubin and Depro Solution
Lot Number 16263034

Ref Number 48559
Exp Date 2017-09-19
Date of Manufacture 2016-09-19

Dil L/N	16263034		Flush L/N	16263034	
	Spec	Result		Spec	Result
Surfactant	N/A	Present	Surfactant	N/A	Present
Buffers	N/A	Present	Preservatives	N/A	Present
Preservatives	N/A	Present			
Depro L/N	16263034		THb Calibrator	16263034	
	Spec	Result		g/dL	16.0
NaOCl %	2.90-3.20%	Pass		g/L	160
				mmol/L	9.92

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. Total Hemoglobin (THb) is traced by using Cyanmethemoglobin method.


Approval

QC Supervisor
Title

12/8/2016
Date