



CERTIFICATE OF ANALYSIS

STP pHoxUltra/CCX CO-Oximeter Cal Cartridge
w/Bilirubin and Depro Solution
Lot Number 16342020

Ref Number 48559
Exp Date 2017-12-07
Date of Manufacture 2016-12-07

Dil L/N	16342020		Flush L/N	16342020	
	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	16342020		THb Calibrator	16342020	
	Spec	Result		g/dL	16.1
NaOCl %	2.90-3.20%	Pass		g/L	161
				mmol/L	10.0

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

2/14/2017

Date