



CERTIFICATE OF ANALYSIS

STP pHoxUltra/CCX CO-Oximeter Controls Auto-Cartridge
Lot Number 23159093

Ref Number 48921
Exp Date 2025-04-11
Date of Formulation 2023-04-11
UDI# (01)00385480489218(11)230411(17)250411(10)23159093

Level 7			Level 8		
	Spec	Pass/Fail		Spec	Pass/Fail
tHb g/dL	5.5-8.5	Pass	tHb g/dL	14.5-17.5	Pass
MetHb %	2.0-8.0	Pass	MetHb %	10.0-20.0	Pass

Level 9		
	Spec	Pass/Fail
tHb g/dL	18.0-22.0	Pass
MetHb %	20.0-30.0	Pass

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. Total Hemoglobin (THb) and MetHemoglobin (metHb) are traceable by using Cyanmethemoglobin method.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Awishi M

Approval

QC Inspector

Title

7/11/2023

Date