



CERTIFICATE OF ANALYSIS

STP pHoxUltra/CCX CO-Oximeter Cal Cartridge
with Bilirubin and Depro Solution
Lot Number 25042038

Ref Number 48559
Exp Date 2026-02-11
Date of Manufacture 2025-02-11
UDI# (01)00385480485593(11)250211(17)260211(10)25042038

Dil L/N	25042038		
	<u>Spec</u>	<u>Result</u>	
Surfactant	N/A	Present	
Buffers	N/A	Present	
Preservatives	N/A	Present	

Flush L/N	25042038		
	<u>Spec</u>	<u>Result</u>	
Surfactant	N/A	Present	
Preservatives	N/A	Present	

Depro L/N	25042038		
	<u>Spec</u>	<u>Result</u>	
NaOCl %	2.90 - 3.20%	Pass	

tHb Calibrator L/N	25042038		
	<u>Spec</u>	<u>Result</u>	
	g/dL	15.9	
	g/L	159	
	mmol/L	9.9	

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) is traced by using Cyanmethemoglobin method.

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

Haneen Aldarwish

Approval

QC Inspector
Title

3/24/2025
Date