



CERTIFICATE OF ANALYSIS

STP pHoxUltra/CCX CO-Oximeter Cal Cartridge
with Bilirubin and Depro Solution
Lot Number 24124035

Ref Number 48559
Exp Date 2025-05-03
Date of Manufacture 2024-05-03
UDI# (01)00385480485593(11)240503(17)250503(10)24124035

Dil L/N	24124035		
	<u>Spec</u>	<u>Result</u>	
Surfactant	N/A	Present	
Buffers	N/A	Present	
Preservatives	N/A	Present	

Flush L/N	24124035		
	<u>Spec</u>	<u>Result</u>	
Surfactant	N/A	Present	
Preservatives	N/A	Present	

Depro L/N	24124035		
	<u>Spec</u>	<u>Result</u>	
NaOCl %	2.90 - 3.20%	Pass	

tHb Calibrator L/N	24124035		
	<u>Spec</u>	<u>Result</u>	
	g/dL	16.3	
	g/L	163	
	mmol/L	10.1	

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

Awishi M

Approval

QC Inspector

Title

6/3/2024

Date