

CERTIFICATE OF ANALYSIS

STP pHOxUltra/CCX CO-Oximeter Cal Cartridge with Bilirubin and Depro Solution Lot Number 24004059

Ref Number 48559
Exp Date 2025-01-04
Date of Manufacture 2024-01-04
UDI# (01)00385480485593(11)240104(17)250104(10)24004059

Dil L/N	24004059		Flush L/N	24004059	
	<u>Spec</u>	Result		<u>Spec</u>	Result
Surfactant	N/A	Present	Surfactant	N/A	Present
Buffers	N/A	Present	Preservatives	N/A	Present
Preservatives	N/A	Present			
5	0.400.40=0			0.400.40=0	
Depro L/N	24004059		tHb Calibrator L/N	24004059	
	<u>Spec</u>	<u>Result</u>	g/dL	16.1	
NaOCI %	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 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

Approval

QC Inspector

Title

2/22/2024

Date