

CERTIFICATE OF ANALYSIS

STP pHOxUltra/CCX CO-Oximeter Cal Cartridge with Bilirubin and Depro Solution Lot Number 24180052

Ref Number 48559
Exp Date 2025-06-28
Date of Manufacture 2024-06-28
UDI# (01)00385480485593(11)240628(17)250628(10)24180052

Dil L/N	24180052		Flush L/N	24180052	
	<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	04400050			0.4400050	
Depro L/N	24180052		tHb Calibrator L/N	24180052	
	<u>Spec</u>	Result	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

Haneen Aldarwish

8/12/2024 Date