



CERTIFICATE OF ANALYSIS

STP CCX CO-Oximeter Reagent Cartridge
w/Bilirubin and Depro Solution
Lot Number 108720

Ref Number 41549
Exp Date 2012-08

Dil L/N	108206		Flush L/N	108720	
	Spec	Result		Spec	Result
Surfactant	N/A	Present	Surfactant	N/A	Present
Buffers	N/A	Present	Preservatives	N/A	Present
Preservatives	N/A	Present			
Depro L/N	108207		THb Calibrator	108206	
	Spec	Result	g/dL	16.1	
NaOCl %	2.90-3.20%	Pass	g/L	161	
			mmol/L	9.98	

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CFR-Part 820, Quality System Regulation (QSR), Current Good Manufacturing Practice (cGMP) and ISO 13485:2003, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications. Total Hemoglobin (THb) is traced by using Cyanmethemoglobin method.

Approval

QC Supervisor

Title

10/27/2011

Date

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