



CERTIFICATE OF ANALYSIS

STP CCX CO-Oximeter Controls Auto-Cartridge
Lot Number 15208015

Ref Number 37598
Exp Date 2017-07

Level 7			Level 8		
	Spec	Pass/Fail		Spec	Pass/Fail
tHb g/dL	5.5-8.5	Pass	tHb g/dL	14.5-17.5	Pass
MetHb %	2.0-8.0	Pass	MetHb %	10.0-20.0	Pass

Level 9		
	Spec	Pass/Fail
tHb g/dL	18.0-22.0	Pass
MetHb %	20.0-30.0	Pass

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 EN ISO 13485:2012, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications. Total Hemoglobin (THb) and MetHemoglobin (methHb) are traceable by using Cyanmethemoglobin method.


Approval

QC Supervisor
Title

8/25/2015
Date

CONFIDENTIAL