

CERTIFICATE OF ANALYSIS

STP Prime Controls Auto QC Cartridge CCS Lot Number 16082022

Ref Number 45150 Exp Date 2017-09

	Level 1		Level 2	
	Spec	Pass/Fail	Spec	Pass/Fail
рН	7.110-7.190	Pass	pH 7.350-7.420	Pass
pCO2 mmHg	55.0-65.0	Pass	pCO2 mmHg 39.0-45.0	Pass
pO2 mmHg	58.0-68.0	Pass	pO2 mmHg 97.0-107.0	Pass
Na+ mmol/L	151.7-161.7	Pass	Na+ mmol/L 136.2-140.2	Pass
K+ mmol/L	5.71-6.01	Pass	K+ mmol/L 3.76-3.96	Pass
CI- mmol/L	126.8-135.8	Pass	Cl- mmol/L 97.9-105.9	Pass
Ca++ mmol/L	1.55-1.63	Pass	Ca++ mmol/L 0.98-1.06	Pass
Glu mg/dL	67-81	Pass	Glu mg/dL 176-206	Pass
Lac mmol/L	0.7-1.3	Pass	Lac mmol/L 2.5-3.1	Pass

	Level 3	
	Spec	Pass/Fail
рН	7.570-7.650	Pass
pCO2 mmHg	18.0-26.0	Pass
pO2 mmHg	135.0-149.0	Pass
Na+ mmol/L	116.6-120.6	Pass
K+ mmol/L	1.75-2.05	Pass
CI- mmol/L	81.2-89.2	Pass
Ca++ mmol/L	0.51-0.61	Pass
Glu mg/dL	275-325	Pass
Lac mmol/L	6.4-7.7	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with 21 CRF-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. All listed analytes are traceable to NIST SRM Materials.

Joyce ansara Approval

QC Supervisor

Title

3/29/2016

Date