



CERTIFICATE OF ANALYSIS

STP Prime Controls Auto QC Cartridge ABG
Lot Number 16082022

Ref Number 53456
Exp Date 2017-09-08
Date of Manufacture 2016-03-08

Level 1		
	Spec	Pass/Fail
pH	7.110-7.190	Pass
pCO2 mmHg	55.0-65.0	Pass
pO2 mmHg	58.0-68.0	Pass

Level 2		
	Spec	Pass/Fail
pH	7.350-7.420	Pass
pCO2 mmHg	39.0-45.0	Pass
pO2 mmHg	97.0-107.0	Pass

Level 3		
	Spec	Pass/Fail
pH	7.570-7.650	Pass
pCO2 mmHg	18.0-26.0	Pass
pO2 mmHg	135.0-149.0	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. All listed analytes are traceable to NIST SRM Materials.


Approval

QC Supervisor
Title

5/11/2016
Date