

## **CERTIFICATE OF ANALYSIS**

EBG Stat Auto QC Cartridge Lot Number 16117016 Ref Number REG00034 Exp Date 2017-10

Level 1		Level 2
Spec	Pass/Fail	Spec Pass/Fa
pH 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
Cl- mmol/L 126.8-135.8	Pass	CI- 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 66-82	Pass	Glu mg/dL 176-206 Pass
Lac mmol/L 0.6-1.0	Pass	Lac mmol/L 2.5-3.1 Pass

Level 3	
Spec	Pass/Fai
7.570-7.650	Pass
18.0-26.0	Pass
135.0-149.0	Pass
116.6-120.6	Pass
1.75-2.05	Pass
81.2-89.2	Pass
0.51-0.61	Pass
275-325	Pass
6.4-7.7	Pass
	Spec 7.570-7.650 18.0-26.0 135.0-149.0 116.6-120.6 1.75-2.05 81.2-89.2 0.51-0.61 275-325

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.

Jayce annaia Approval

QC Supervisor

Title

5/17/2016 Date