



CERTIFICATE OF ANALYSIS

StatSensor Creatinine Linearity Kit
Lot Number 5515279990

Ref Number 44037
Exp Date 2017-10

Linearity Level 1	Lot: 5515274241	Exp: 2017-10
	Spec	Mean Result
Creatinine mg/dL	0.9-1.1	1.0

Linearity Level 2	Lot: 5515275242	Exp: 2017-10
	Spec	Mean Result
Creatinine mg/dL	1.4-2.6	2.0

Linearity Level 3	Lot: 5515275243	Exp: 2017-10
	Spec	Mean Result
Creatinine mg/dL	3.0-5.1	4.4

Linearity Level 4	Lot: 5515289244	Exp: 2017-10
	Spec	Mean Result
Creatinine mg/dL	5.5-7.0	6.2

Linearity Level 5	Lot: 5515279245	Exp: 2017-10
	Spec	Mean Result
Creatinine mg/dL	9.5-11.0	10.7

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.


Approval

QC Supervisor
Title

11/3/2015
Date