



**CERTIFICATE OF ANALYSIS**

StatSensor Creatinine Linearity Kit  
Lot Number 5522297990

Ref Number 44037  
Exp Date 2024-10-24  
Date of Manufacture 2022-10-24

**Linearity Level 1**

Lot: 5522297241 Exp: 2024-10-24

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	0.90 - 1.10	1.06

**Linearity Level 2**

Lot : 5522298242 Exp: 2024-10-25

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	1.95 - 2.25	2.07

**Linearity Level 3**

Lot: 5522305243 Exp: 2024-11-01

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	3.80 - 4.30	4.10

**Linearity Level 4**

Lot: 5522305244 Exp: 2024-11-01

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	5.50 - 7.00	6.00

**Linearity Level 5**

Lot: 5522305245 Exp: 2024-11-01

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	9.50 - 11.00	10.00

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector

Title

01/17/2023

Date