



CERTIFICATE OF ANALYSIS

StatSensor Creatinine Linearity Kit
Lot Number 5524295990

Ref Number 44037
Exp Date 2026-10-21
Date of Manufacture 2024-10-21

Linearity Level 1

Lot: 5524295241 Exp: 2026-10-21

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	0.90 - 1.10	1.02

Linearity Level 2

Lot :5524295242 Exp: 2026-10-21

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	1.95 - 2.25	2.08

Linearity Level 3

Lot: 5524295243 Exp: 2026-10-21

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

Linearity Level 4

Lot: 5524296244 Exp: 2026-10-22

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	5.50 - 7.00	5.86

Linearity Level 5

Lot: 5524296245 Exp: 2026-10-22

	<u>Spec</u>	<u>Mean Result</u>
Creatinine mg/dL	9.50 - 11.00	9.85

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

Auishi M

Approval

QC Inspector

Title

11/11/2024

Date