



**CERTIFICATE OF ANALYSIS**

Nova Creatinine / BUN / Hct Linearity STD Levels 1 - 4  
Lot Number 26007025

Ref Number 61656  
Exp Date 2027-01-05

Date of Manufacture 2026-01-05

UDI# (01)00385480616560(11)260105(17)270105(10)26007025

Level 1 L/N 26005016  
Level 1 Exp Date 2027-01-05

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	78.0 - 82.0	Pass
Creatinine mg/dL	10.8 - 11.2	Pass
Hct %	13 - 17	Pass

Level 2 L/N 26005017  
Level 2 Exp Date 2027-01-05

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	51.7 - 54.3	Pass
Creatinine mg/dL	6.9 - 7.1	Pass
Hct %	28 - 32	Pass

Level 3 L/N 26006008  
Level 3 Exp Date 2027-01-06

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	29.3 - 30.8	Pass
Creatinine mg/dL	4.5 - 4.7	Pass
Hct %	44 - 48	Pass

Level 4 L/N 26006009  
Level 4 Exp Date 2027-01-06

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	5.9 - 6.2	Pass
Creatinine mg/dL	0.98 - 1.02	Pass
Hct %	62 - 66	Pass

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. All listed analytes are traceable to NIST SRM Materials.

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

*Auishi.M*

Approval

QC Inspector  
Title

01/29/2026  
Date