



CERTIFICATE OF ANALYSIS

Nova Creatinine / BUN / Hct Linearity STD Levels 1 - 4
Lot Number 26132066

Ref Number 61656
Exp Date 2027-06-15

Date of Manufacture 2026-06-15

UDI# (01)00385480616560(11)260615(17)270615(10)26132066

	Level 1 L/N	26166013	
	Level 1 Exp Date	2027-06-15	
	<u>Spec</u>	<u>Pass/Fail</u>	
BUN mg/dL	83.9 - 88.2	Pass	
Creatinine mg/dL	10.8 - 11.2	Pass	
Hct %	13 - 17	Pass	

	Level 2 L/N	26166014	
	Level 2 Exp Date	2027-06-15	
	<u>Spec</u>	<u>Pass/Fail</u>	
BUN mg/dL	56.6 - 59.5	Pass	
Creatinine mg/dL	6.9 - 7.1	Pass	
Hct %	28 - 32	Pass	

	Level 3 L/N	26167001	
	Level 3 Exp Date	2027-06-16	
	<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	26167002	
	Level 4 Exp Date	2027-06-16	
	<u>Spec</u>	<u>Pass/Fail</u>	
BUN mg/dL	5.9 - 6.2	Pass	
Creatinine mg/dL	0.98 - 1.02	Pass	
Hct %	61 - 65	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

Approval

QC Inspector
Title

06/30/2026
Date