



CERTIFICATE OF ANALYSIS

Nova StatStrip Hb/Hct Linearity Solutions Levels 1 - 3

Ref Number 59826

Lot Number 8124201990

Exp Date 2026-07-19

Date of Manufacture 2024-07-19

UDI# (01)00385480598262(11)240719(17)260719(10)8124201990

Level 1 L/N	8124201241			Level 2 L/N	8124204242		
Level 1 Exp Date	2026-07-19			Level 2 Exp Date	2026-07-22		
	<u>Spec</u>	<u>Mean Result</u>			<u>Spec</u>	<u>Mean Result</u>	
Hb g/dL	8.2 - 8.8	8.6		Hb g/dL	13.4 - 14.6	14.2	
Hct %	24 - 26	25		Hct %	38 - 42	41	
Level 3 L/N	8124204243						
Level 3 Exp Date	2026-07-22						
	<u>Spec</u>	<u>Mean Result</u>					
Hb g/dL	18.4 - 19.6	18.7					
Hct %	52 - 58	54					

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

8/23/2024

Date