



CERTIFICATE OF ANALYSIS

Nova StatStrip Hb/Hct Linearity Solutions Levels 1 - 3

Ref Number 59826

Lot Number 8126176990

Exp Date 2028-06-25

Date of Manufacture 2026-06-25

UDI# (01)00385480598262(11)260625(17)280625(10)8126176990

Level 1 L/N 8126176241
Level 1 Exp Date 2028-06-25

	<u>Spec</u>	<u>Mean Result</u>
Hb g/dL	8.2 - 8.8	8.8
Hct %	24 - 26	26

Level 2 L/N 8126177242
Level 2 Exp Date 2028-06-26

	<u>Spec</u>	<u>Mean Result</u>
Hb g/dL	14.2 - 15.8	14.9
Hct %	42 - 47	42

Level 3 L/N 8126177243
Level 3 Exp Date 2028-06-26

	<u>Spec</u>	<u>Mean Result</u>
Hb g/dL	18.4 - 19.6	19.8
Hct %	52 - 58	58

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

Awishi.M

Approval

QC Inspector

Title

7/15/2026

Date