



CERTIFICATE OF ANALYSIS

Bioprofile Basic 4 Reagent Pack
Lot Number 413414

Part Number 37645
Exp Date 2025-08-31

Std A L/N 24134014

	<u>Spec</u>	<u>Result</u>
Gluc g/L	0.9 - 1.1	Pass
Lac g/L	0.9 - 1.1	Pass
Gln mmol/L	0.9 - 1.1	Pass
Glu mmol/L	0.4 - 0.6	Pass

Std B L/N 24134014

	<u>Spec</u>	<u>Result</u>
Gluc g/L	4.5 - 5.5	Pass
Lac g/L	2.7 - 3.3	Pass
Gln mmol/L	4.5 - 5.5	Pass
Glu mmol/L	1.75 - 2.25	Pass

Std C L/N 24134014

	<u>Spec</u>	<u>Result</u>
Gluc g/L	14.3 - 15.7	Pass
Lac g/L	4.5 - 5.5	Pass
Glu mmol/L	4.5 - 5.5	Pass

Std D L/N 24134014

	<u>Spec</u>	<u>Result</u>
Buffered Diluent	N/A	Present

Flush L/N 24134014

	<u>Spec</u>	<u>Result</u>
Aqueous Salt Solution	N/A	Present

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. The following analytes are traceable to NIST SRM Materials: Gluc, Lac.

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

Approval

QC Inspector
Title

6/18/2024
Date