



CERTIFICATE OF ANALYSIS

Stat Profile Prime Ampuled Controls
Lot Number 24123023

Ref Number 52714
Exp Date 2025-10-30
Date of Manufacture 2024-04-30
UDI# (01)00385480527149(11)240430(17)251030(10)24123023

Table with 3 columns: Analyte, Spec, Pass/Fail. Level 1 L/N: 24121010, Level 1 Exp Date: 2025-10-30. Rows include pH, pCO2 mmHg, pO2 mmHg, Hct %, Na+ mmol/L, K+ mmol/L, Cl- mmol/L, Ca++ mmol/L, Glu mg/dL, Lac mmol/L.

Table with 3 columns: Analyte, Spec, Pass/Fail. Level 2 L/N: 24121011, Level 2 Exp Date: 2025-10-30. Rows include pH, pCO2 mmHg, pO2 mmHg, Hct %, Na+ mmol/L, K+ mmol/L, Cl- mmol/L, Ca++ mmol/L, Glu mg/dL, Lac mmol/L.

Table with 3 columns: Analyte, Spec, Pass/Fail. Level 3 L/N: 24121012, Level 3 Exp Date: 2025-10-30. Rows include pH, pCO2 mmHg, pO2 mmHg, Hct %, Na+ mmol/L, K+ mmol/L, Cl- mmol/L, Ca++ mmol/L, Glu mg/dL, Lac mmol/L.

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. SO2 is traced to tonometry.

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

Approval

QC Inspector
Title

5/29/2024
Date