

CERTIFICATE OF ANALYSIS

Allegro HbA1c Test Cartridge Lot Number 24347010

rridge Ref Number 54215 Exp Date 2025-12-12 Date of Manufacture 2024-12-12 UDI# (01)00385480542159(11)241212(17)251212(10)24347010

Ctl Level 1 Ctl Level 2

SpecPass/FailSpecPass/FailHbA1c %4.9 - 6.7PassHbA1c %8.1 - 11.7Pass

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.

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

Approval

QC Inspector

Title

12/18/2024

Date