

CERTIFICATE OF ANALYSIS

Allegro HbA1c Test Cartridge Lot Number 24170005

tridge Ref Number 54215 Exp Date 2025-06-18 Date of Manufacture 2024-06-18 UDI# (01)00385480542159(11)240618(17)250618(10)24170005

Ctl Level 1 Ctl Level 2

 Spec
 Pass/Fail
 Spec
 Pass/Fail

 HbA1c %
 4.9 - 6.7
 Pass
 HbA1c %
 8.1 - 11.7
 Pass

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

6/21/2024 Date