SIEMENS
Healthineers

MANUFACTURER ADDRESS:
SIEMENS HEALTHCARE DIAGNOSTICS INC.
511 BENEDICT AVENUE
TARRYTOWN, NY 10591 USA
REGISTRATION ADDRESS:
SIEMENS HEALTHCARE DIAGNOSTICS INC.
430 S. BEIGER STREET
MISHAWAKA, IN 46544 USA

Certificate of Analysis

PRODUCT DESCRIPTION: DCA System HbA1c Reagent Kit	
MATERIAL NUMBER:	10698915 (10698915)
LOT NO.	0712034
QUANTITY:	15,595 PC
EXPIRATION DATE: (YYYY-MM-DD)	2026-03-31
MANUFACTURE DATE: (YYYY-MM-DD)	2024-03-26

This product was certified by the responsible Quality organization to conform to the performance and Quality System requirements of Siemens Healthcare Diagnostics.

The product listed and manufactured by Siemens Healthcare Diagnostics in Mishawaka, IN, USA has been made, tested and approved through all stages to comply with "Good Manufacturing Practices" requirements and the product specifications as published:

Characteristic	Target Value	Result
CAL CARD	-	Pass
Calibrators Precision	-	Pass
CARTRIDGE Assembly	-	Pass
Master Curve - B		2.31
Master Curve - K		132
Master Curve - RO		0.9432
Master Curve - Z		-0.9081
F. P. MFG PKG	-	Pass
Procedure PIWI-00027-MSH	-	Pass
Procedure Rev.		17.0
F. P. Reconcilliation	-	Pass
Review & approve test results	-	Pass
File Sample	-	Pass
%Error Resolution Level 1	<=9	5
%Error Resolution Level 2	<=9	4
%Error Resolution Level 3	<=9	6
%Bias Level 1 (5% HbA1c)	<=3.0	-1.7

This document was produced by an electronic system, which was designed and validated to comply with the FDA 21 CFR Part 11 electronic records and signatures.

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Characteristic	Target Value	Result
%Bias Level 2 (8% HbA1c)	<=2.0	-1.3
%Bias Level 3 (11% HbA1c)	<=3.0	-1.8
%CV Level 1 (5% HbA1c)	<=3.3	1.6
%CV Level 2 (8% HbA1c)	<=3.3	1.2
%CV Level 3 (11% HbA1c)	<=3.3	1.9

APPROVAL:

SIGNATURE INFORMATION
NAME OF APPROVER: Kami Gunnoe
Quality Assurance Representative
DATE AND TIME OF APPROVAL/RELEASE: 2024-04-04 08:35:48
Made usage decision for inspection lot 400000701809

Quality Department

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