CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW210007

B. Parent Document Number

K214117

C. CLIA Waiver Type:

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

D. Applicant

Abbott Diagnostics Technologies AS

E. Proprietary and Established Names

Afinion™ HbA1c, Afinion™ 2 and Alere Afinion™ AS100 Analyzer

F. Measurand (analyte)

Glycated hemoglobin (% hemoglobin A1c, % HbA1c)

G. Sample Type(s)

Venous and capillary (fingerstick) whole blood

H. Type of Test

Quantitative, automated boronate affinity immunoassay

I. Test System Description

1. Overview

The Afinion HbA1c is a fully automated boronate affinity assay for the determination of the percentage of hemoglobin A1c in human venous and capillary whole blood. Each assay cartridge contains blue boronic acid conjugate, a tube with a polyethersulfone membrane, and washing solution (morpholine buffered sodium chloride solution with detergents and preservative). Each cartridge is labeled with a unique barcode.

This device was previously cleared for use on the Afinion AS100 Analyzer (K050574, K110056, K151809), on the Afinion 2 analyzer (K171650) and with the Afinion HbA1c Controls (K050574) and CLIA waived (K050574/A001) for use with capillary and venous (EDTA, heparin, citrate or NaF) human whole blood. The current submission is for updates to the package insert and quick reference guide for the Afinion HbA1c on the Alere Afinion AS100 Analyzer (K151809) and the Afinion HbA1c on the Afinion 2 analyzer (K171650). The modifications to the labeling include updates to the interfering substances and cross-reactants, inclusion of limitations, updates to the out-of-range HbA1c error messages, inclusion of minor changes to the instructions for use and to simplify some of the language in the labeling. To support that the modified device is simple and has an insignificant risk of an erroneous results, the sponsor performed a risk analysis and developed and validated the fail-safe and failure alert mechanism described below.

J. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-safe Mechanisms

1. Risk Analysis

   A risk analysis was conducted to identify and evaluate hazards related to the modifications of the Afinion HbA1c assay label for the 2 analyzers (Afinion 2 and the Alere Afinion AS100). All risks of harm to the patient or operator were mitigated to an acceptable level, and were supported by the fail-safe and flex studies, and a readability assessment of the revised labeling described below.

2. Fail-Safe and Failure Alert Mechanisms

   Results outside reportable range: A software update was made to how values outside the HbA1c measuring range are reported. Depending on the software version of the analyzer, for out-of-range results, the user will get an alert either through an information code and the corresponding interpretation in the QRG or package insert, or through a message directly displayed on the screen, e.g., "«HbA1c <4.0% »" or "«HbA1c >15.0%»". Regardless of the software version, no HbA1c result will be displayed.

3. Flex Studies

   Flex study – Quality control mixing using a vortex: A flex study was conducted to evaluate mixing quality control materials using vortex as an alternative to mixing by thorough shaking for 30 seconds. The original product labeling instructs the operator to mix the control well by thoroughly shaking the vial for 30 seconds. The modified instructions provide an alternative mixing method and state that the controls can be mixed for 30 seconds using a vortex. For the study, control samples were either thoroughly shaken for 30 seconds (control method), vortexed for 30 seconds, or vortexed for 9 minutes. Each condition was then tested in six replicates. The study found that the test results relative to the control method were not affected when vortexing the control sample for 30 seconds or 9 minutes and supports the labeling instructions.

K. Labeling for Waived Devices

The labeling consists of:

1. One Package Insert for both analyzers
2. Two Quick Reference Guides- one for the HbA1c assay on each analyzer
3. Two Instrument Manuals – one for each analyzer

The following elements are appropriately present:

1. The Package insert, and Quick Reference Guides as determined by the Flesch-Kincaid readability test, have been written at no higher than a 7th grade reading level. Pictures and diagrams have been provided, as appropriate.
2. The User's Manual, Package Insert and Quick Reference Guides identify the HbA1c test as CLIA waived.
3. The User's Manual, Quick Reference Guides, and test cartridge package insert contain a statement that a Certificate of Waiver is required to perform the test in a waived setting.
4. The User's Manual, Package Insert, and Quick Reference Guides contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test as required by 42 CFR 493.15(e)(1).
5. The User's Manuals, Package Insert, and Quick Reference Guides provide instructions for conducting quality control procedures.
6. The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.