510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K214117

B Applicant

Abbott Diagnostics Technologies AS

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LCP	Class II	21 CFR 864.7470 - Glycosylated Hemoglobin Assay	HE - Hematology
JQT	Class I	21 CFR 862.2400 - Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as K214117 and CW210007. This 510(k) is for a modification to a cleared device.

B Measurand:

Glycosylated Hemoglobin (HbA1c)

C Type of Test:

Quantitative colorimetric boronate affinity immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:

Afinion™ HbA1c

Afinion™ HbA1c is an in-vitro diagnostic test for quantitative determination of glycated hemoglobin (%hemoglobin A1c, % HbA1c) venous and capillary human whole blood. The measurement of % HbA1c is recommended as a marker of long term metabolic control in persons with diabetes mellitus.

Afinion™ 2

Afinion™ 2 analyzer is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ test cartridges. Afinion™ 2 system, consisting of Afinion™ 2 analyzer and Afinion™ test cartridges is for in vitro diagnostic use only.

Alere Afinion™ AS100 Analyzer

Alere Afinion™ AS100 Analyzer with Alere Afinion™ Data Connectivity Converter (ADCC) is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ Test Cartridges. The ADCC is a small device for automatic transfer of data, including patient and control assay results, from the Alere Afinion™ Analyzer to a laboratory information system or another electronic journal system.

Alere Afinion™ AS100 Analyzer System, consisting of Alere Afinion™ AS100 Analyzer with Alere Afinion™ Data Connectivity Converter (ADCC), Afinion™ Test Cartridges and Afinion™ Controls is for in vitro diagnostic use only.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
For in vitro diagnostic use
For Point of Care use.

D Special Instrument Requirements:

For use with the Afinion™ 2 and the Alere Afinion™ AS100 Analyzer

IV Device/System Characteristics:

A Device Description:

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.

The Afinion HbA1c is factory calibrated and intended for use with the previously cleared Afinion AS100 Analyzer (K050574, K110056, K151809), the Afinion 2 (K171650) and the Afinion HbA1c Controls (K050574).

B Principle of Operation:

Afinion™ HbA1c is a fully automated boronate affinity assay. The test Cartridge contains all of the necessary reagents. The sample is collected with the integrated sampling device and the Test Cartridge is placed in the cartridge chamber of the analyzer. The blood sample is then automatically diluted and mixed with a solution that releases hemoglobin from the erythrocytes. The hemoglobin precipitates. This sample mixture is transferred to a blue boronic acid conjugate, which binds to the cis-diols of glycated hemoglobin. This reaction mixture is soaked through a filter membrane and all precipitated hemoglobin, conjugate bound and unbound (i.e., glycated and non-glycated hemoglobin) remains on the membrane. Any excess of conjugate is removed with washing reagent.

The analyzer evaluates the precipitate on the membrane. By measuring the reflectance, the blue (glycated hemoglobin) and the red (total hemoglobin) color intensities are evaluated. The ratio between them is proportionate to the percentage of HbA1c in the sample. The % HbA1c is displayed on the Afinion™ AS100 Analyzer and the Afinion™ 2.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Alere Afinion™ HbA1c and ACR on Afinion™ 2 analyzer

B Predicate 510(k) Number(s):

K171650

C Comparison with Predicate(s):

Device & Predicate Device(s):	K214117	K171650
Device Trade Name	Afinion™ HbA1c Afinion™ 2 Afinion™ AS100 Analyzer	Afinion™ HbA1c Afinion™ 2 analyzer
General Device Characteristic Similarities		
Intended Use/Indications For Use	Afinion HbA1c is an in vitro diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, % HbA1c). The measurement of % HbA1c is recommended as a marker of long term metabolic control in persons with diabetes mellitus.	Same
Assay principle	Quantitative colorometric boronate affinity immunoassay	Same
General Device Characteristic Differences		
Analyzer	Alere Afinion™ AS100 Analyzer and Afinion™ 2	Afinion™ 2 analyzer
Sampling from Control Vial	Mix the control well by thoroughly shaking the vial for 30 seconds. You may also use a vortex mixer for 30 seconds.	Mix the control material thoroughly by shaking the vial for 30 seconds.

Device & Predicate Device(s):	K214117			K171650	
Results outside reportable range	Code 105 106	Cause HbA1c below 4.0% HbA1c above 15%	Comment If your analyzer has software version 21.10 or higher, this code will not be displayed. The results will be shown as «HbA1c <4.0% » If your analyzer has software version 21.10 or higher, this code will not be displayed. The results will be shown as «HbA1c <15.0% »	Code 105 106	Cause HbA1c below 4.0% HbA1c above 15%

VI Standards/Guidance Documents Referenced:

ISO 14971 Medical devices - Application of risk management to medical devices

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in K050574

2. Linearity/ assay reportable range:

   Linearity was previously established for the range of 4.00 – 15.00 % HbA1c in K050574.

3. Analytical Specificity/Interference:

Interference was evaluated and found to support the sponsor's claims, included in the candidate labeling, that there is no significant interference (≤7%) up to the following concentrations:

Substance	Highest concentration tested with no significant interference
Acetaminophen	20 mg/dL
Acetylcysteine	166 mg/dL
Acetylsalicylic acid	100 mg/dL
Ampicillin	100 mg/dL
Ascorbic acid	30 mg/dL
Bilirubin –conjugated	60 mg/dL
Bilirubin - unconjugated	60 mg/dL
Cefoxitin	250 mg/dL
Cholesterol	351 mg/dL
Cyclosporine A	0.5 mg/dL
Cyclosporine C	0.5 mg/dL
Doxycyclin	5 mg/dL
Fructosamine	680 µmol/L
Glucose	1000 mg/dL
Glyburide	0.19 mg/dL
Heparin	5000 U/L
Ibuprofen	50 mg/dL
Intralipid	1000 mg/dL
Levodopa	2 mg/dL
Metformin	4 mg/dL
Methyldopa	2 mg/dL
Metronidazole	20 mg/dL
Phenylbutazone	40 mg/dL
Rheumatoid factor	780 000 IU/L
Rifampicin	6.4 mg/dL
Salicylic acid	59 mg/dL
Theophylline	10 mg/dL
Total protein	150 g/L
Triglycerides	1389 mg/dL

Cross reactivity with Hemoglobin Derivatives

Potential cross reactivity with acetylated hemoglobin, carbamylated hemoglobin, labile HbA1c, and glycated albumin was evaluated and found to support the sponsor's claims, included in the candidate labeling, that there is no cross reactivity with acetylated hemoglobin (4.6 mg/mL), carbamylated hemoglobin (13.8 mg/mL), labile HbA1c (11.4 mg/mL), or glycated albumin (7.7 mg/mL).

Hemoglobin Variant Interference

Hemoglobin variant testing demonstrated no significant interference for Hemoglobin A2 (≤ 5.7%), Hemoglobin S (≤ 42%), Hemoglobin C (≤ 36%), Hemoglobin E (≤ 26%), Hemoglobin D (≤ 42%) and Hemoglobin F (≤10.4%). The sponsor's definition of non-significant interference is ≤7% mean relative deviation between the candidate method and the comparator method.

The labeling of the candidate HbA1c assay was updated to reflect these results as well as the following: "The highest HbF concentration where no significant interference (= 7%) is observed is 10.4% HbF. Above 10.4% HbF, a negative interference is observed".

4. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The Afinion HbA1c assay is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method for Measurement of HbA1c. The Afinion HbA1c assay is certified with the National Glycohemoglobin Standardization Program (NGSP).

5. Detection Limit:

   The Afinion HbA1c assay reportable range is 4.0-15.0% HbA1c as established in K050574.

6. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Performance was established in K050574

2. Matrix Comparison:
   Matrix comparison was evaluated in K050574

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The following is included in the labeling:

Recommendations from American Diabetes Association (ADA):
A reasonable goal for many nonpregnant adults with diabetes is HbA1c < 7.0% (53 mmol/mol). More or less stringent glycemic goals may be appropriate for individual patients. Goals should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations.

American Diabetes Association. Glycemic Target. Diabetes Care 2019;42(Suppl. 1):S61-S70

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.