Employee Health

Clinic Alere Afinion HbA1c

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| Effective Date: November 2021 | Department: Laboratory |
| Date of Review: November 2023 | Approval: Laboratory Management |

1. **Intended Use**

Afinion HbA1c is an *in vitro* diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in human capillary and venous whole blood. The measurement of percentage HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus1.

1. **Summary and Explanation of the Test**

The human erythrocyte is freely permeable to glucose. Within each erythrocyte, a slow, continuous, non-enzymatic process between hemoglobin A and various sugars takes place. The product formed is known as glycated hemoglobin, or glyco-hemoglobin2.

The chronic elevated blood sugar level of persons with diabetes mellitus will over time cause damage to the small vessels of the body. This damage develops slowly over years and is known to cause late complications3.

Good metabolic control, i.e. lowering the percentage HbA1c, has proven to delay the onset and slowing the progression of diabetes late complications3, 4, 5.

1. **Test Principle**

Afinion HbA1c is a fully automated boronate affinity assay for the determination of the percentage of hemoglobin A1c in human whole blood.

The Afinion HbA1c Test Cartridge contains all of the reagents necessary for the determination of % HbA1c. The sample material is collected with the integrated sampling device before the test cartridge is placed in the cartridge chamber of the Afinion 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 a 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 being proportional to the percentage of HbA1c in the sample. The % HbA1c is displayed on the Afinion Analyzer.

1. **Standardization**

Afinion HbA1c is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method for Measurement of HbA1c. HbA1c values are reported according to the National Glycohemoglobin Standardization Program (NGSP) recommendations at DCCT (Diabetes Control and Complications Trial) level7.

Afinion HbA1c is certified by NGSP.

1. **Specimen Collection and Handling  
   Specimen Materials and Storage**

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| 1. SPECIMEN: | The following sample materials can be used with the Afinion HbA1c test:   * Capillary blood sample (from finger prick). * Venous whole blood with anticoagulants (ethylene diamine tetra-acetic acid (EDTA), heparin or citrate). |
| 1. SPECIMEN STORAGE: | **Specimen storage**   * Capillary blood samples cannot be stored. * Venous whole blood with anticoagulants (EDTA, heparin or citrate) can be stored refrigerated for 10 days or at room temperature 18-30°C (64-86°F) for 8 hours. Do not freeze. * Consult the Afinion HbA1c Control Package Insert for storage of control materials. |
| 1. HANDLING PRECAUTIONS: | **Note!**  Diluted samples cannot be used with Afinion HbA1c.  Coagulated or hemolyzed samples cannot be used with Afinion HbA1c. An information code will be displayed and no result obtained if hemolyzed or coagulated samples are analyzed. |

1. **Reagents And Materials**
2. **Materials provided (contents per 15 tests unit)**

15 Test cartridges packed separately in foil pouches with a desiccant bag

1 Package insert

1. **Materials required, but not provided with the kit**

* Alere Afinion AS100 Analyzer (REF 1115175/1115390)
* Afinion HbA1c Control (REF 1116975)
* Standard blood collection equipment
* Afinion User Manual (provided with the analyzer)
* Afinion HbA1c Quick Guide (provided with the analyzer)

Electronic copies of Afinion User Manuals and Quick Guidelines are available at www.globalpointofcare.abbott

1. **Description of the test cartridge**

The main components of the test cartridge are the sampling device (1) and the reaction container (3). The test cartridge has a handle (4), a barcode label with lot specific information (5) and an ID area for sample ID (7). See Figure 1 below.



**Figure 1** Afinion HbA1c Test Cartridge.

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| **Component** | **Function/composition** |
| 1. Sampling device    1. Closed position    2. Lifted position | For collection of patient sample or control. |
| 1. Capillary | 1.5 μL plastic capillary to be filled with sample material. |
| 1. Reaction container 2. Conjugate 3. Membrane tube 4. Washing solution 5. Reconstitution reagent 6. Empty | Contains reagents necessary for one test:  Blue boronic acid conjugate.  Tube with polyethersulfone membrane.  Morpholine buffered sodium chloride solution with detergents and preservative.  HEPES buffered sodium chloride with lysis and precipitation agents.  N/A |
| 1. Handle | For correct finger grip. |
| 1. Barcode label | Contains assay- and lot-specific information for the analyzer. |
| 1. Optical reading area | Area for transmission measurement. |
| 1. ID area | Space for written or labeled sample identification. |

1. **Storage and Stability**

**Refrigerated storage 2-8**°**C (36-46**°**F)**

* The Afinion HbA1c Test Cartridges are stable until the expiration date only when stored refrigerated. The expiration date is stated on the foil pouch and on the kit box.
* The Afinion HbA1c Test Cartridge must reach an operating temperature of 18-30°C (64-86°F) before use. Upon removal from refrigerated storage, leave the test cartridge in the unopened foil pouch for at least 15 minutes. No test results will be displayed and no test result obtained if the test cartridge is too cold when used.
* Do not freeze.

**Room temperature storage 15-25**°**C (59-77**°**F)**

* The Afinion HbA1c Test Cartridges can be stored in unopened foil pouches at room temperature for 90 days. Note the date of removal from the refrigerator and the new expiration date on the kit container.
* Avoid exposure to direct sunlight.

**Opened foil pouch**

* The test cartridge should be used within 10 minutes after opening.
* Avoid exposure to direct sunlight.

1. **Specimen Collection**

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| **Blood sampling from finger**   * Always use gloves. * Clean the finger using alcohol. Allow the area to air dry. * Use a lancet and firmly prick the finger (a). Properly dispose the lancet. * Allow a good drop of blood to form before sampling (b). * Apply direct pressure to the wound site with a clean gauze pad. |  |
| **Sampling from a tube**   * Patient samples stored refrigerated can be used without equilibration to room temperature. * Mix the sample material well by inverting the tube 8-10 times before collecting a sample. |  |
| **Sampling from the AFINION™ HbA1c Control vial**   * Allow the control material to reach ambient operating temperature (18‑30°C, 64‑86°F) before use, which takes approximately 45 minutes. * Mix the control material thoroughly by shaking the vial for 30 seconds. A Vortex mixer may be used. * Extract a sample from the vial or the cap. |  |
| **Important!**   * Bring the tip of the capillary just beneath the surface of the blood drop/sample material as shown in figures (c), (d) and (e). * Be sure that the capillary is completely filled as shown in figure (f). It is not possible to overfill the capillary. Avoid air bubbles. * Do not wipe off the capillary. |  |

1. **Test Procedure**

Consult the Afinion HbA1c Quick Guide for detailed instructions on how to collect and analyze a patient sample or control.

**Test procedure overview**

1. Switch on the AfinionAnalyzer.
2. Allow the Afinion HbA1c Test Cartridge to reach operating temperature 18‑30°C (64‑86°F). Open the foil pouch just before use.
3. Be sure to properly label the test cartridge with sample ID.   
   The test cartridge has a dedicated ID area.
4. Collect a specimen following the specimen collection procedure described below. Once the capillary is filled, analysis of the test cartridge must start within 1 minute.
5. Insert the test cartridge in the analyzer. The analysis time is approximately 3.5 minutes.
6. Record the test results in the proper place according to the laboratory guidelines. The results will be stored in the analyzer electronic result records.
7. Remove the test cartridge from the analyzer.

**Important!**

* Do not use test cartridges that have been accidentally dropped on the floor or lab bench after specimen collection.
* Do not used cold test cartridges.
* Use the test cartridge within 10 minutes after opening the foil pouch.
* Analysis of the test cartridge must start within 1 minute after the capillary is filled with sample material.

1. **Result Interpretation**

**Test Result Reporting**

Afinion HbA1c measures the total glycated hemoglobin and the total hemoglobin concentration. The ratio between them is proportional to the % HbA1c of the sample. The analyzer calculates the ratio, and the test result is displayed as % HbA1c.

1. Patient results are documented in Labdaq software.
2. Upon documenting result, lot number and expiration date will be indicated according to test site utilization.
3. Testing personnel will verify information prior to acceptance.

**Reportable Range**

**The Afinion HbA1c reportable range is 4.0-15.0% HbA1c.0**

**The HbA1c results are displayed in 0.1% intervals.**

**The hemoglobin measuring range is 6-20 g/dL.**

If the patient’s HbA1c or hemoglobin value is outside range, no test result will be reported and the corresponding information code will be displayed. If accurate results outside the Afinion HbA1c range are required, the sample must be analyzed using another method.

**Values Outside the HbA1c Measuring Range**

Valid for SW ≤ 7.03 (Afinion AS100):

If the patient’s HbA1c value is outside the measuring range, no test result will be reported and an information code will be displayed (see “Troubleshooting”).

Valid for SW ≥ 7.04 (Afinion AS100):

* HbA1c < 4.0% is displayed if the HbA1c value is below the measuring range
* HbA1c > 15.0% is displayed if the HbA1c value is above the measuring range

**Expected Values**

Recommendations from the 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 considerations9.

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| --- | --- |
| % HbA1c | Interpretation of results |
| 4-6 | Non-Diabetic Range |
| 7 | ADA Target |
| 8-12 | Above Target |

ADA: American Diabetes Association

**Interpretation of results**

Despite a reliable internal process control of the analysis, each individual test result should be interpreted with careful consideration to the patient’s medical history, clinical examinations and other laboratory results. If the test result is questionable or if clinical signs and symptoms appear inconsistent with the test result, analyze the Afinion HbA1c Controls and re-test the sample using a new Afinion HbA1 Test Cartridge.

1. **Quality Control**

Quality control testing should be done to confirm that the Afinion Analyzer System is working properly and providing reliable results. Only when controls are used routinely and the values are within acceptable ranges can accurate results be assured for patient samples.

Each laboratory site can benefit from establishing a quality control plan. The laboratory director should determine whether additional testing is appropriate for their laboratory.

It is recommended to keep a permanent record of all quality control results. The Afinion Analyzer automatically stores the control results in a separate record. Consult the Afinion Analyzer User Manual.

**Control material**

Afinion HbA1c Control is recommended for routine quality control testing. Consult the Afinion HbA1c Control Package Insert.

**Frequency of control testing**

Controls should be analyzed:

* with each new shipment of Afinion HbA1c test kits.
* with each new lot of Afinion HbA1c test kits.
* at least every 30 days.
* when training new operators in correct use of the Afinion HbA1c and the Afinion Analyzer.
* anytime an unexpected test result is obtained.

Make sure to test controls in compliance with any local, state and/or federal regulations. CLIA waived laboratories should follow the manufacturer’s quality control guidelines.

**Verifying the control results**

The measured value should be within the acceptable limits stated for the control. Consult the Afinion HbA1c Control Package Insert.

If the measured value is outside the acceptable limits, make sure that:

* patient samples are not analyzed
* the control vial is not expired.
* the control vial has not been in use for more than 60 days.
* the control vial has been stored according to recommendations.
* Afinion HbA1c Test Cartridges have been stored according to recommendations.
* there is no visual sign of bacterial or fungal contamination of the control vial.

Correct any procedural error and retest the control material.

If *no* procedural errors are detected:

* investigate the frequency of control failures.
* examine the laboratory’s quality control records.
* ensure that there is no trend in out-of-range quality control results.
* retest the control material using a new control vial.
* patient results must be declared invalid. Contact customer service for advice. Do not analyze patient samples

1. **Troubleshooting**

To ensure that correct HbA1c results are reported, the Afinion Analyzer performs optical, electronic and mechanical controls. The capillary, the test cartridge and all individual processing steps are checked during the course of each analysis. When problems are detected, the analyzer terminates the test and displays an information code.

The table below contains the assay specific information codes. Consult the Afinion Analyzer User Manual for information codes not listed in this table:

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| --- | --- | --- |
| CODE # | | CAUSE |
| 103 | The hemoglobin concentration is below 6.0 g/dL | |
| 104 | The hemoglobin is above 20.0 g/dL | |
| 105 | The HbA1c value is below 4.0% | |
| 106 | The HbA1c value is above 15.0% | |

Follow the actions listed in the user manual to correct the error.

**Important!**

The manufacturer must be notified of any test system that is perceived or validated to be outside of the performance specifications outlined in the instructions.

**Technical support**

The manufacturer provides a toll free line for technical support.   
**Call 1-866-216-9505.** The toll free number is available for use only in the United States of America.

E-mail: [Afinion.Support@abbott.com](mailto:afinion.support@alere.com)

1. **Warnings and Precautions**

* For *in vitro* diagnostic use.
* Do not use test cartridges after the expiration date.
* Do not use test cartridges that have not been stored in accordance with recommendations.
* Do not use the test cartridge if the foil pouch or the test cartridge itself has been damaged.
* Each foil pouch contains a desiccant bag with 1 g silica gel. This material shall not be used in the assay. Discard the desiccant bag in a suitable container. Do not swallow.
* Do not use the test cartridge if the desiccant bag is damaged and desiccant particles are found on the test cartridge. Do not wipe off.
* Do not touch the test cartridge optical reading area (figure 1).
* Do not reuse any part of the test cartridge.
* The test cartridge contains sodium azide (<0.1%) as a preservative. In case of leakage from the test cartridge, avoid contact with eyes and skin.
* The used test cartridges, sampling equipment, patient samples and controls are potentially infectious and should be disposed of immediately after use. Proper handling and disposal methods should be followed in accordance with local, state and federal regulations. Use personal protective equipment.

1. **Limitations of the Test**

* Any cause of shortened erythrocyte life span will reduce exposure of erythrocytes to glucose, resulting in a decrease in HbA1c values, regardless of the method used. Caution should be used when interpreting the HbA1c results from patients with conditions such as hemolytic anemia or other hemolytic diseases, homozygous sickle cell trait, pregnancy, blood loss, polycythemia, iron deficiency etc.
* Diluted samples cannot be used with Afinion HbA1c.
* Coagulated or hemolyzed samples cannot be used with Afinion HbA1c. Samples with >14% (2000 mg/dL) hemolysis may return an information code.
* If the sample has a hemoglobin value below 6.0 g/dL or above 20.0 g/dL, no test results will be reported and an information code will be displayed.

1. **Interference**

NO significant interference (<5%) was observed up to the following concentrations:

• Bilirubin 342 µmol/L (20 mg/dL)

• Triglycerides 15.7 mmol/L (1389 mg/dL)

• Cholesterol 9.1 mmol/L (351 mg/dL)

• Glucose 27.8 mmol/L (500 mg/dL)

• Fructosamine 680 µmol/L

• Hemolysis 5.0%

• Anticoagulants (EDTA, heparin and citrate) at concentrations normally used in blood collection tubes.

Over-the-counter and prescription drugs:

• Acetaminophen 1.7 mmol/L (256 µg/mL)

• Ibuprofen 1.8 mmol/L (372 µg/mL)

• Acetylsalicylic acid 3.3 mmol/L (599 µg/mL)

• Salicylic acid 4.3 mmol/L (593 µg/mL)

• Glyburide 3.9 µmol/L

• Metformin 310 µmol/L

No significant interference (<5%) was observed at expected serum levels for the above-mentioned drugs.

**Important!**

It is possible that other substances and/or factors not listed above may interfere with the test and cause false results.

1. **Performance Characteristics**

The performance data presented in this section are representative data from internal and external studies. Results obtained in individual laboratories may vary.

1. **Analytical specificity**

The following hemoglobin (Hb) variants have been analyzed and found not to affect the Afinion HbA1c test result: HbAC, HbAD, HbAE, HbF, HbAJ and HbAS6. Carbamylated hemoglobin does not affect the Afinion HbA1c test result6. Pre-glycated hemoglobin does not affect the Afinion HbA1c result.

1. **References**
2. Lenzi S et al.,The Clinical Usefulness of Glycated Hemoglobin in Monitoring Diabetes Mellitus: A long-Term Study. Clin Chem 1987; 33:55-56.
3. Frantzen F, Studies on glycated hemoglobin and new analytical methods for its determination. Dr. philos. thesis. NTNU,Trondheim 1998. ISBN 82-7861-116-5.
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       5. Hoelzel W et. Al., IFCC reference system for measurement of hemoglobin A1c in human blood and the national standardization schemes in the United States, Japan and Sweden: a method comparison study. Clin Chem 2004; 50(1):166-174.
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