

# Blanchard Valley Health System: Point of Care Testing

## Abbott Afinion2 - Hemoglobin A1c

### 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-hemoglobin<sup>2</sup>.

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 complications<sup>3</sup>. Good metabolic control, i.e. lowering the % HbA1c, has proven to delay the onset and slowing the progression of diabetes late complications<sup>3,4,5</sup>.

### 2. 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.

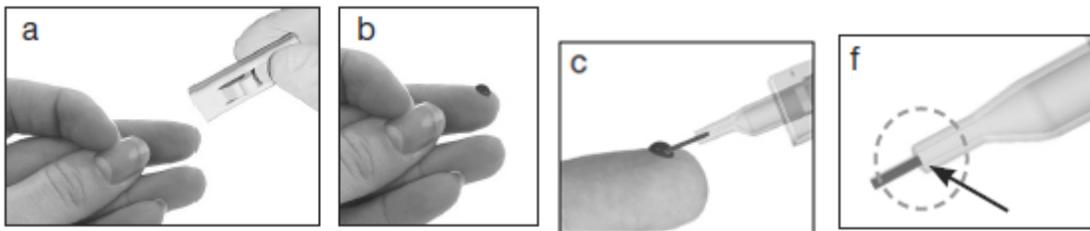
The analyzer evaluates the precipitate on the membrane. By measuring the reflectance, the blue (glycated hemoglobin) and the red (total hemoglobin) color intensities are evaluated, the ratio between them being proportional to the percentage of HbA1c in the sample. The % HbA1c is displayed on the Afinion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

### 3. Specimen Collection and Handling

#### Specimen Materials and Storage

#### A. Specimen

- Capillary blood sample (from finger prick)
- Venous whole blood with anticoagulants: EDTA, Heparin or Citrate



#### B. Specimen Storage

- Capillary blood samples cannot be stored.
- Venous whole blood with anticoagulants (EDTA, heparin, or citrate) may be stored as follows:
  - Refrigerated (2–8°C / 36–46°F): up to 10 days
  - Room temperature (18–30°C / 64–86°F): up to 8 hours
  - Do not freeze specimens.

#### C. Handling Precautions

- Diluted samples cannot be used with the Afinion HbA1c test.

- Coagulated or hemolyzed samples cannot be used. If such samples are analyzed, an information code will display and no result will be produced.

#### 4. Reagents And Materials

##### Materials provided (contents per 15 tests unit)

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

1 Package insert

##### Materials required, but not provided with the kit

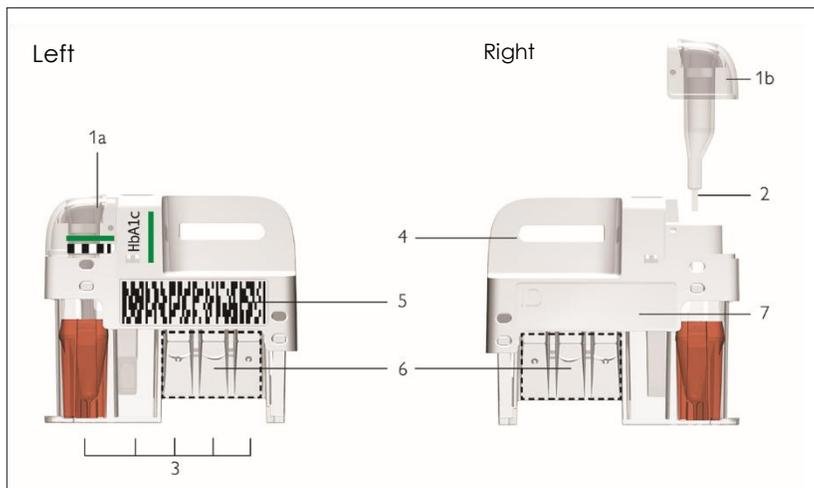
Afinion 2 Analyzer

Afinion HbA1c Control (REF 1116975)

Standard blood collection equipment

##### 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.



Component	Function/Composition
1 Sampling device:	For collection of patient sample or control (1a - closed position, 1b - lifted position).
2 Capillary:	Capillary to be filled with sample material.
3 Reaction wells:	Contain all necessary reagents for one test.
4 Handle:	For correct finger grip.
5 Barcode label:	Contains assay and lot-specific information for the analyzer.
6 Optical reading area:	Area for transmission measurement.
7 ID area:	Space for written or labelled sample identification.

#### 5. 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.

### **6. 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.

#### **Control material**

Afinion HbA1c Control ( CI and CII)

#### **Storage and Stability:**

Refrigerated 2-8°C

Unopened

- Stable until manufacturer's expiration date.

Opened

- Stable for 60 days, Record open date and 60 day open expiration date on the vials.
- Replace the cap immediately after use.
- Always store the control vials refrigerated 2-8°C (36-46°F) when not in use
- Store in upright position

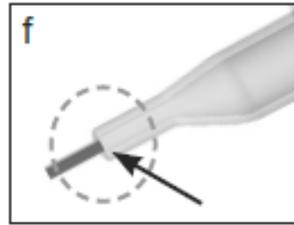
#### **Frequency of control testing**

Controls should be analyzed:

- with each new shipment/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.

#### **QC Test Procedure**

- Allow the control material to reach room temperature 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.
- Inspect the vial and ensure that the solution is homogenous.
- Collect a sample using the Afinion HbA1c Test Cartridge sampling device. The sample can be extracted from the vial or the cap. Ensure the capillary is completely filled. Avoid air bubbles. DO NOT wipe the capillary. It is not possible to overfill the capillary



- carefully insert the capillary back into the test cartridge until it snaps
- The test must be started within 1 minute of filling the capillary.



- Press the blue Quality Control icon
- The lid opens automatically. Insert the test cartridge. The barcode should face left.
- Tap the door to close.



- Select the blue Control ID to enter the lot number and select enter
- Scan the corresponding barcode in the package insert OR, manually type the lot number from the vial into the analyzer.
- When analysis is complete, the machine will beep, and the value will appear on the screen.



- Record the result when it appears on the screen. Touch to accept.
- The lid opens automatically. Remove and discard the cartridge. Close the lid manually.
- Clean the outside of the control vial neck and replace the cap.
- Immediately return the control vial back to the refrigerator after use.

### Verifying the control results

The measured value should be within the acceptable limits stated for the control  
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 the control is still outside the acceptable limits, contact BVH Point of Care Coordinator. Call 419-423-5247

### Do not analyze patient samples

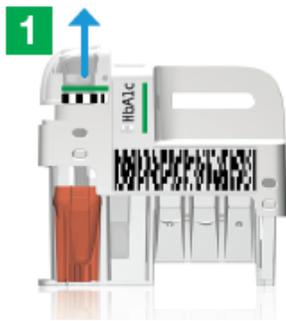
## 7. Warnings and Precautions

- 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).

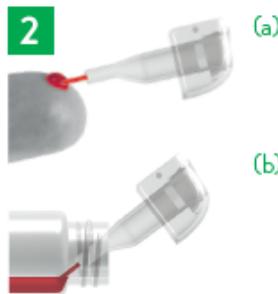
- Do not reuse any part of the test cartridge.
- The test cartridge contains sodium azide (<0.1%) as a preservative. In case of leakage from the test cartridge, avoid contact with eyes and skin.
- The used test cartridges, sampling equipment, patient samples and controls are potentially infectious and 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.

## 8. Test Procedure

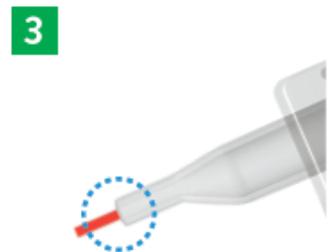
- Switch on the Afinion Analyzer.
- Allow the Afinion HbA1c Test Cartridge to reach operating temperature 18-30°C (64-86°F). Open the foil pouch just before use.
- Properly label the test cartridge with sample ID.
- Lift the capillary sampling device out of the cartridge.
- Collect a specimen following the specimen collection procedure described below



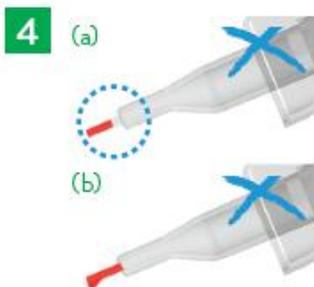
Pull up the sampling device.



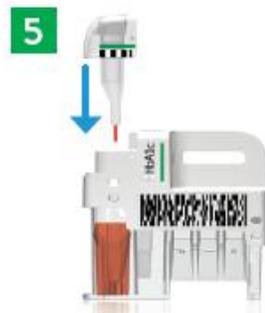
Touch the surface of the blood drop (a) or control (b).



Fill the capillary to the end. It is not possible to overfill.



Avoid air bubbles and incomplete filling (a). Avoid sample on the outside of the capillary (b). Do not wipe off.



Insert the sampling device immediately.



Within 1 minute place the test cartridge in the analyzer.

- Touch  for patient samples
- The lid opens automatically. Insert the test cartridge. The barcode should face left.
- Close the lid manually to start the test
- Touch  and enter patient ID. Touch  to confirm.
- Record the result when it appears on the screen. Touch  to accept.
- The lid opens automatically. Remove and discard the cartridge. Close the lid manually.

### **Important!**

- Do not use test cartridges that have been accidentally dropped on the floor or lab bench after specimen collection.
- Do not use 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.

## **9. Result Interpretation**

### **BVH Reference Range**

Normal : 4.0 - 5.6%

Prediabetes : 5.7 - 6.4%

Diabetes : > 6.5%

### **Reportable Range**

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

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**

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").

- 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 considerations<sup>9</sup>.

### **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.

### **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 HbAS<sup>6</sup>. Carbamylated hemoglobin does not affect the Afinion HbA1c test result<sup>6</sup>. Pre-glycated hemoglobin does not affect the Afinion HbA1c result.

## **10. Maintenance**

### **Cleaning the exterior**

Cleaning the exterior of the Afinion 2 Analyzer should be performed whenever necessary. Most spills and stains can be removed with water or a mild detergent.

- Power off the analyzer. Unplug the power supply when the shut down procedure is completed.

- Clean the outside of the analyzer and the touch display with a clean, lint-free and non-abrasive cloth dampened in water or a mild detergent.
- To disinfect the exterior of the analyzer use a 1:10 solution of household bleach (i.e., 0.5% sodium hypochlorite), 2% glutaraldehyde solution or 70% alcohol solution. The surface of the analyzer should be exposed to the disinfectant for at least 10 minutes.
- Allow the analyzer to air dry.
- Plug in the power supply and power on the analyzer.

#### **Cleaning the cartridge chamber**

The Cleaning Kit should always be used for cleaning the cartridge chamber. The cartridge chamber should be cleaned immediately if materials or liquids are spilled in the cartridge chamber. For regular maintenance (removal of dust particles etc.), the cartridge chamber should be cleaned every 30 days.

- Touch  to open the lid.
- Unplug the power supply.
- Wet a Cleaning Swab with 3 drops of water and gently rinse the cartridge chamber. To disinfect the surface, use a 1:10 solution of household bleach (i.e., 0.5% sodium hypochlorite), 2% glutaraldehyde solution or 70% alcohol solution). Do not soak.
- Carefully remove spills and particles from the cartridge chamber using the moistened swab.
- To disinfect the cartridge chamber, the surface of the chamber should be exposed to the disinfectant for at least 10 minutes
- Wipe off any residual liquid from the cartridge chamber using a new, dry Cleaning Swab.
- Plug in the power supply, and power on the analyzer by pressing the on/off button.
- The lid will close automatically during the self-test. If it doesn't, then close it manually and restart the analyzer.

### **11. 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.

### **12. 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.

**13. PROCEDURAL NOTES:**

This test is waived under CLIA '88 regulations. If a laboratory modifies the test system instructions, then the test is considered high complexity and subject to all CLIA requirements. A CLIA Certificate of Waiver is needed to perform CLIA waived testing.

**14. References**

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13. Abbott Afinion2 HbA1c Quick Guide, 1116934 Rev. A 2018/12, Abbott Diagnostics Technologies AS, NO-0504 Oslo, Norway

**Laboratory Director Approval**

Approved by \_\_\_\_\_ Date \_\_\_\_\_