



**ARROWHEAD REGIONAL MEDICAL CENTER**  
**Department of Ambulatory Care Services**  
**Primary Care Clinic Policies and Procedures**

**Policy No. 550.00 Issue 1**  
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**SECTION: PATIENT CARE**

**SUB SECTION: DIAGNOSTIC TESTS AND POINT OF CARE**

**SUBJECT: AFINION HbA1c ANALYZER**

**APPROVED BY:** \_\_\_\_\_

Clinical Director, Ambulatory Services

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## **POLICY**

Hemoglobin A1c (HbA1c) tests are performed by Primary Care Clinic (PCC) clinical staff: Registered Nurse (RN), Licensed Vocational Nurse (LVN), and Care Assistant (CA). The testing is performed using the Afinion HbA1c Analyzer. Afinion HbA1c is an *in vitro* diagnostic test for quantitative determination of glycosylated hemoglobin (% HbA1c) in human whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus.

## **PROCEDURES**

- I. Quality Control Testing.
  - A. Quality control testing is done to confirm that the Afinion Analyzer System is working properly and providing reliable results.
  - B. Frequency of control testing. Controls are analyzed:
    1. With each new shipment of Afinion HbA1c test kits.
    2. With Each new lot of Afinion HbA1c test kits.
    3. A minimum of every 30 days.
    4. When training new operators in correct use of the Afinion HbA1c and the Afinion Analyzer.
    5. Anytime an unexpected test result is obtained.
  - C. Verify Control results are within the acceptable limits documented in the Afinion HbA1c Control Package Insert. If results are outside acceptable limits:
    1. Do not use the analyzer for patient samples until both Control Levels are within acceptable limits.
    2. The Control Vials have not passed their expiration date.
    3. Opened Control Vials have not been in use for more than 60 days
    4. The Control Vials and Afinion HbA1c Test Cartridges have been stored according to recommendations.
    5. There is no visual sign of bacterial or fungal contamination of the Control Vial.
  - D. Correct any procedural error and retest the control material.

1. Retest the control material using a New Control Vial.
2. Retest Control Material using New Afinion HbA1c Test Cartridges.

E. Storage, Stability, and Handling:

1. Refrigerated storage 2-8°C (36-46°F)
  - a. Unopened Control Vials are stable until expiration date indicated on the vial label when stored refrigerated.
  - b. Opened Control Vials are stable for 60 days when stored refrigerated.
    - 1) It is recommended to note the date of opening and the new expiration date on the vial label and on the kit label.
  - c. Afinion HbA1c Test Cartridges are stable until the expiration date only when stored refrigerated in sealed foil pouches.
  - d. The expiration date is stated on the foil pouch and on the outer container.
  - e. Afinion HbA1c Test Cartridges must reach an operating temperature of 18-30°C (64-86°F) before use.
    - 1) Upon removal from refrigerated storage, leave the test cartridge in the unopened foil pouch for at least 15 minutes.
    - 2) Information code 210 will be displayed, and no test result is obtained if the test cartridge is too cold when used.
    - 3) Do not freeze.
2. Room temperature storage 15-25°C (59-77°F)
  - a. Store the Afinion™ HbA1c Cartridges in the upright position to avoid bubbles in the reaction wells.
  - b. Afinion HbA1c Test Cartridges can be stored in unopened foil pouches at room temperature for 90 days.
  - c. Note on the date of removal from the refrigerator and the new expiration date on the kit container or the individual unopened Afinion HbA1c Test Cartridges
    - 1) Avoid exposure to direct sunlight
3. Opened Foil Pouch
  - a. The test cartridge should be used within 10 minutes after opening.
  - b. Once the capillary is filled, analysis of the test cartridge must start within 1 minute of collection
  - c. Avoid exposure to direct sunlight

F. The Alere Afinion™ AS 100 Analyzer/Afinion™ 2 Analyzer must be placed on a flat level surface avoiding any equipment which may emit vibrations.

G. Always hold Cartridges by the handle to avoid fingerprints, blood, or dirt on the optical reading area and barcode label.

II. Performing Quality Control

## A. Internal Process Control.

1. A self-test is performed during start-up of the analyzer to ensure that the instrument is operating according to established specifications. The self-test validates:
  - a. Hardware and software integrity.
  - b. Test cartridge transport system.
  - c. Liquid transport system.
  - d. Camera vision system.

## B. External Process Control.

1. Patient ID.
  - a. The Afinion 2 patient ID functionality will, if configured, allow up to four patient ID fields to be entered. The patient ID will be stored with each patient test result in the result records.
2. Operator ID.
  - a. The Afinion 2 operator functionality will, if configured, require the operators to log in before testing. The functionality may also prevent unauthorized operators to login, perform tests and configuration. The operator ID will be stored with each test result in the result records.
3. Quality Control Lockout.
  - a. The Afinion 2 QC lockout function allows you to configure the instrument to automatically enforce your local required frequency of control testing.
  - b. If the required control test has not been performed or the control result is outside the acceptable range, the instrument will disable patient testing for this assay.
  - c. See manufacturer recommendations.

C. Only when controls are used routinely, and the values are within acceptable ranges can accurate results be assured for patient samples.

D. Switch on the Afinion Analyzer

E. Allow the control material to reach an ambient operating temperature of 18-30°C (64-86°F) before use, which takes approximately 45 minutes.

F. Place unopened Afinion HbA1c Test Cartridges from the refrigerator out at room temperature for at least 15 minutes.

G. Wash Hands and put on gloves.

H. Mix the control material thoroughly by shaking the vial for 30 seconds.

1. Inspect the vial and confirm the solution is homogenous.
  - a. confirm there is no control residue adhering to the bottom of the vial prior to collection.

- I. Pull the sampling device straight up from the test cartridge. Test cartridges to be used within 10 minutes of being opened.
  1. Hold the test cartridge by the handle.
  2. Fill the Cartridge Sampling capillary tip completely with Control Solution 1.
  3. Afinion HbA1c test sample volume is 1.5 microliters.
  4. Tilt the Control Solution Vial and place the tip of the capillary tip just beneath the surface of the Control Solution.
  5. Avoid air bubbles and any excess sample material on the outside of the capillary.
  6. Do not wipe off the capillary
  7. Analysis of the test cartridge must start within 1 minute of collection.
  8. Replace the sampling device immediately into the test cartridge.
  9. Touch the Blue Control Sample icon for running a control sample. The instrument lid opens automatically.
  10. Insert the test cartridge with the barcode facing left.
  11. Close the lid manually to start analyzing the Control sample.
  12. Touch the Blue Bottle icon and enter the Control Solution ID.
  13. Touch the Enter Arrow icon to confirm.
  14. Record the result when it appears on the screen.
  15. The measured value should be within the acceptable range stated in the Afinion HbA1c Control Package insert.
    - a. On occasion an information code is displayed instead of a result.
    - b. See the Afinion II Analyzer User Manual for the meanings of the information code.

- I. Touch the Green Check mark to accept results.
- J. The instrument lid opens automatically.
- K. Remove and immediately discard the used test cartridge.
- L. Close the instrument manually when the Analyzer is not in use.

1. After collecting a Control Sample, clean the outside neck of the vial, replace the cap, and immediately place the Control Vial back in the refrigerator.

M. Repeat procedure for Control Solution 2

N. Afinion 2 Control Levels acceptable Range Values are provided in the HbA1c kit.

O. The Control Values for Level 1 and Level 2 must be within the acceptable range limits prior to performing patient testing.

1. The lot numbers of the Control Levels 1 and 2 must match the lot numbers used for Acceptable Range values.

### III. Performing a Patient Sample.

A. Confirm order from Practitioner

B. Confirm quality control performed within manufacturer guidelines and Control Levels 1 and Level 2 are within range values provided for the lot numbers included in the kit.

C. Perform 2-patient identifiers

- D. Wash hands and put on gloves.
- E. Prepare patient for sampling.
  - 1. To ensure the best results when obtaining a finger stick sample follow this step-by-step procedure. A warm hand and good blood flow are essential to collect a capillary sample.
    - a. Wash the patient's hand in warm water.
    - b. Gently massage the finger from base to tip several times.
  - 2. Select a skin puncture site on one of the center fingers of either hand at the side of the finger pad.
  - 3. Clean the finger using alcohol and allow the area to air dry.
  - 4. Choose a suitable lancet depth and firmly prick the finger at the selected site.
    - a. Squeeze the finger gently to obtain a drop of blood.
    - b. Wipe away the first drop of blood.
    - c. Squeeze the finger gently again until a second large free-flowing drop of blood forms.
      - 1) Do not milk the finger
      - 2) Excessive squeezing of the finger may cause an erroneous result.
- F. Pull the sampling device/capillary tip straight up from the test cartridge.
- G. Hold the sampling device tilted slightly higher than the patient's finger and touch the surface of the blood drop.
  - 1. Fill the capillary completely with a patient sample avoid air bubbles.
  - 2. It is not possible to overfill the capillary.
  - 3. Avoid any excess sample on the outside of the capillary. Do not wipe off the capillary.
  - 4. Do not tilt the sampling device downwards.
- H. Replace the sampling device carefully into the test cartridge.
- I. Analysis of the test cartridge must start within one minute.
- J. To run a patient sample test cartridge, touch the Orange Patient Sample icon.
- K. The instrument lid opens automatically. Remember never try to open the lid manually.
- L. Insert the test cartridge carefully with the barcode facing left.
- M. Close the lid manually to start analyzing.
- N. If the patient ID function is enabled touch the Orange Patient ID icon and enter the patient ID.
- O. Touch the Enter arrow icon to confirm.
- P. The test result appears in three minutes. Record the result when it appears on the screen.
- Q. The last 500 results are stored in memory and can be viewed in the main menu.

- R. If a printer is connected, the Print icon will appear, and you can print the test result.
- S. Touch the Green Accept icon to accept the result.
- T. The instrument lid opens automatically. Never try to open the lid manually.
- U. Remove and immediately discard the used test cartridge.
- V. Close the lid manually when the analyzer is not in use.
- W. To interpret the test result please read the package insert carefully.
- X. Venous samples may be used directly from the refrigerator.
  - 1. Venous whole blood (with Ethylenediamine tetraacetic acid (EDTA), heparin, citrate or sodium fluoride (NaF)).
  - 2. Venous whole blood with anticoagulants (except NaF) can be stored refrigerated for 10 days or a room temperature for 8 hours.
  - 3. Do not analyze hemolyzed, coagulated, or diluted samples.
  - 4. Mix the sample by gently inverting the tube eight to ten times before use.
  - 5. Remove the cap of the tube.
  - 6. Then remove the sampling device from the cartridge
  - 7. Tilt the tube and place the tip of the capillary just beneath the surface of the sample material.
  - 8. Watch the blood fill the capillary completely avoiding air bubbles and any excess sample on the outside of the capillary.
  - 9. It is not possible to overfill the capillary.
  - 10. Do not wipe off the capillary.
  - 11. Replace the sampling device immediately into the test cartridge and complete the procedure as described for finger stick samples.

#### IV. Result Interpretation

##### A. Test Result Reporting

- 1. The Afinion HbA1c reportable range is 4.0-15.0% HbA1c.
- 2. The HbA1c results are displayed in 0.1% intervals.
- 3. The hemoglobin measuring range is 6-20 g/dL.
- 4. It is recommended to send a sample for laboratory testing on patients with an Afinion HbA1c value of  $\geq$  (greater than or equal to) 10.0 %.
- 5. 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.
- 6. If the codes listed below are displayed, it is recommended to send a venous blood sample to the laboratory for A1c testing.
  - a. Code 103: The hemoglobin concentration is below 6.0 g/dL
  - b. Code 104: The hemoglobin is above 20.0 g/dL
  - c. Code 105: The Hb A1c value is below 4.0 %
  - d. Code 106: The HbA1c value is above 15.0%
- 7. For the display of codes 103 and 104, it is recommended to additionally order a hemoglobin and hematocrit (H&H) or a complete blood count (CBC).

8. If accurate results outside the Afinion HbA1c range are required, the sample must be analyzed using another method.
9. 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.
10. 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.

V. Expected Results

A. Recommendations from the American Diabetes Association (ADA):

1. A reasonable goal for many nonpregnant adults with diabetes is HbA1c < (less than) 7.0% (53 mmol/mol).

**REFERENCES:**            **Abbott laboratories insert revision: 1116917 Revision A 2019/01**  
**Afinion 2 Analyzer User Manual 2018**  
**Afinion HbA1c Quick Guide 2018**  
**Technical Support Call 1-866-216-9505; email Afinion.support@alere.com**

**DEFINITIONS:**            **Afinion HbA1c is waived under the Clinical Laboratory Improvement Amendment (CLIA) of 1988 (CLIA '88). A CLIA Certificate of Waiver is needed to perform testing in a waived setting.**

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

**Afinion HBA1c is a fully automated boronate affinity assay for the determination of the percentage of hemoglobin A1c in human whole blood. 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.**

**ATTACHMENTS:**            **N/A**

<b>APPROVAL DATE:</b>	<u>3/11/2025</u>	<b>Kristy Byers, Clinical Director II</b> Department/Service Director, Manager or Supervisor
	<u>3/11/2025</u>	<b>Ambulatory Work Group</b> Applicable Administrator, Hospital or Medical Committee
	<u>3/18/2025</u>	<b>Nursing Standards Committee</b> Applicable Administrator, Hospital or Medical Committee
	<u>3/26/2025</u>	<b>Patient Safety and Quality Committee</b> Applicable Administrator, Hospital or Medical Committee
	<u>5/1/2025</u>	<b>Quality Management Committee</b> Applicable Administrator, Hospital or Medical Committee
	<u>5/29/2025</u>	<b>Medical Executive Committee</b> Applicable Administrator, Hospital or Medical Committee
	<u>3/10/2026</u>	<b>Board of Supervisors</b> Approved by the Governing Body

**REPLACES:** N/A

**EFFECTIVE:** 5/29/2025

**REVISED:** N/A

**REVIEWED:** N/A