Keywords: Afinion, Afinion 2, AS100, glycohemoglobin, HbA1c, hemoglobin A1c, POCT

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Appendix A: HbA1c QC Log Sheet: Afinion AS100 and Afinion 2 Analyzers  
Appendix B: Troubleshooting Flowchart  
Appendix C: Afinion AS100 and Afinion 2 Initial Competency Assessment Checklist  
Appendix D: Afinion AS100 Operator's Guide  
Appendix E: Afinion 2 Operator's Guide

I. PURPOSE

This procedure provides instructions for performing Hemoglobin A1c (HbA1c) testing using the Afinion™ AS100 Analyzer and Afinion™ 2 Analyzer. Afinion™ HbA1c is an in vitro diagnostic test for quantitative determination of glycated hemoglobin (% HbA1c) in whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus.
II. ORDER
A physician’s order, standard protocol, or order by another health professional authorized to request laboratory testing is required for point-of-care HbA1c testing.

III. MATERIALS

<table>
<thead>
<tr>
<th>Reagents/Controls</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Afinion HbA1c Test Cartridges</td>
<td>Central Stores (SAP #113419)</td>
</tr>
<tr>
<td>Abbott Afinion HbA1c Control Solutions (Level 1 &amp; 2)</td>
<td>Central Stores (SAP #166135)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supplies</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposable Gloves</td>
<td></td>
</tr>
<tr>
<td>Alcohol Wipes</td>
<td></td>
</tr>
<tr>
<td>Sterile Gauze</td>
<td></td>
</tr>
<tr>
<td>Safety Lancets</td>
<td></td>
</tr>
<tr>
<td>Biohazard Sharps Container</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equipment (Afinion™ 2)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Afinion 2 Analyzer</td>
<td>POC</td>
</tr>
<tr>
<td>Power Cable and Adapter</td>
<td>POC</td>
</tr>
<tr>
<td>Interface Cables</td>
<td>POC</td>
</tr>
<tr>
<td>Barcode Scanner</td>
<td>POC</td>
</tr>
</tbody>
</table>
IV. STORAGE AND HANDLING REQUIREMENTS

<table>
<thead>
<tr>
<th>Test Kit</th>
<th>Temperature</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afinion™ HbA1c Test Kits</td>
<td>Refrigerated (2-8°C)</td>
<td>Manufacturer’s expiration date.</td>
</tr>
<tr>
<td></td>
<td>Room Temperature (15-25°C)</td>
<td>90 days or manufacturer's expiration date, whichever comes first.</td>
</tr>
<tr>
<td>Afinion™ HbA1c Controls</td>
<td>Refrigerated (2-8°C)</td>
<td>Unopened: Manufacturer’s expiration date.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Opened: 60 days or manufacturer’s expiration date, whichever comes first.</td>
</tr>
<tr>
<td>Alere Afinion™ AS100 Analyzer</td>
<td>15-32°C</td>
<td>N/A</td>
</tr>
<tr>
<td>Abbott Afinion™ 2 Analyzer</td>
<td>15-32°C</td>
<td>N/A</td>
</tr>
</tbody>
</table>

A. Once a box of test cartridges is brought to room temperature, the box must be labeled with the room temperature open date and new expiration date in the spaces provided.
B. Once controls are opened, the box must be labeled with the open date and the new expiration date in the spaces provided.
C. Never use test cartridges or controls past their expiration date.
D. Do not store cartridges or controls in direct sunlight, allow to freeze, or allow prolonged exposure to temperatures above 30°C.
E. Cartridges must be stored upright at all times.
F. Allow controls to reach the operating temperature of 18-30°C before use; this takes approximately 45 minutes.
G. Discard QC vial(s) if there is evidence of microbial or fungal contamination.
H. Opened control vials should be stored in an upright position, and recapped and returned to the refrigerator immediately after use.

V. SPECIMEN TYPE
A. Capillary blood sample collected from a fingerstick.
B. A single test requires 1.5 µL of whole blood.

VI. SPECIMEN COLLECTION AND HANDLING
A. Patient identity must be verified using two unique identifiers, neither of which may be the Room Number, prior to sample collection and testing.
B. Refer to PHLEB024: Capillary Blood Collection (Heelstick and Fingerstick) for specific instructions on proper fingerstick technique.
   1. NOTE: No fasting or special diet is necessary prior to testing HbA1c.
C. Remove the sampling device from the test cartridge by placing the cartridge on the testing surface then lifting straight up on the sampling device (see Figure 1).
D. To fill the capillary, hold the sampling device nearly horizontally and bring the tip of the capillary into contact with the patient sample or QC material.
   1. NOTE: Do not wipe off the outside of the capillary tube, as this may wick sample.
   2. NOTE: Avoid air bubbles in the capillary tube.
E. Immediately and carefully replace the sampling device into the test cartridge.

1. NOTE: Once the capillary tube is filled, analysis of the test cartridge must begin within 1 minute.

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: Contains 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 labeled sample identification.

Figure 1

VII. INTERFERING SUBSTANCES

Hemoglobin variants have been analyzed and found to not affect the Afinion™ HbA1c test result, including HbAC, HbAD, HbAE, HbF, HbAJ, and HbAS.

VIII. SAFETY PRECAUTIONS

A. Follow ICPM IFC023 Infection Control and Prevention: Standard and Transmission-based Isolation Precautions.
B. All patient specimens, QC materials, and test cartridges must be considered potentially infectious, handled with care, and disposed of in a JHMI-approved biohazard receptacle.
C. Refrigeration used for reagents and QC materials may be used only as designated.
D. Temperatures of refrigeration used for reagents and QC material are to be monitored, and documentation of that monitoring must be kept readily available for review.
E. The Test Cartridges contain sodium azide as a preservative at a concentration of <0.1%, which is below that which is considered hazardous in normal use. In case of leakage, avoid contact with eyes and skin; wash with plenty of water.
IX. PERFORMING QUALITY CONTROL (QC) TESTS

A. Two levels of Afinion™ HbA1c Controls, Level 1 and Level 2, must be performed:
   1. At least once a week on each instrument in use.
   2. When opening a new lot of Afinion™ HbA1c test kits.
   3. When patient results are questionable.
   4. When training new operators.
   5. At least once a year by each operator to demonstrate ongoing competency.

B. Procedure:
   1. Prepare QC and Test Cartridges:
      a. Verify that the Controls and Test Cartridges are dated and within both the manufacturer's expiration date and open expiration date.
      b. Allow the QC vials to reach ambient operating temperature (18-30° C) before use (approximately 45 minutes).
      c. If the Test Cartridges have been removed from the refrigerator, allow them to reach ambient operating temperature before use (approximately 15 minutes).
   2. Prepare the Analyzer:
      a. If the analyzer is turned off, Press the On/Off button.
         i. On the Afinion™ AS100, the power button is located at the back right on the top of the analyzer.
         ii. On the Afinion™ 2, the power button is located at the back left on the top of the analyzer.
      b. The system will complete a self-test.
         i. NOTE: If an analyzer remains powered on 24/7, the self-test will be completed daily at 3:00am.
      c. Every seven (7) days, the Afinion™ AS100 and Afinion™ 2 systems will execute a QC lockout.
         i. The QC lockout status is displayed at all times on the top right of the screen.
         ii. indicates that QC has been performed within the last 168 hours (7 days), and must be completed before patient testing is allowed.
         iii. indicates that 10% or less of the configured 168 hours is remaining before QC lockout occurs. Patient testing can be performed at any point.
         iv. indicates that QC has been performed within the last 168 hours (7 days), and patient testing can be performed at any point.
   3. Enter Testing Information into the Analyzer:
      a. Scan your JHED ID at the prompt for operator ID, then select the Enter icon.
      b. Select the blue control mode icon . The lid will open automatically and the screen will prompt you to "Insert cartridge".
         i. NOTE: On the Afinion™ AS100 analyzer, the lid opens in an upwards fashion.
         ii. NOTE: On the Afinion™ 2 analyzer, the lid opens by sliding outward.
Subject
Hemoglobin A1c Using the Afinion AS100 and Afinion 2 Analyzers

4. Perform the Test:
   a. Mix the controls by vigorously shaking the vial for at least 30 seconds.
   b. Inspect the vial and ensure that the solution is homogenous. If it is not, continue vigorously shaking.
   c. Open a test cartridge and remove it from the foil pouch by holding it by the handle.
      i. NOTE: The test cartridge must be used within 10 minutes.
   d. Collect a sample of QC material using the test cartridge sampling device by following the steps in Section VI: Specimen Collection and Handling.
      i. NOTE: The sample may be extracted from the vial or the cap (recommended).
      ii. NOTE: Once the capillary is filled with QC material, testing must start within 1 minute.
      iii. NOTE: If the Test Cartridge is accidentally dropped after filling the capillary tube, discard the test cartridge and repeat specimen collection.
   e. Insert the test cartridge with the barcode label facing left into the cartridge chamber of the analyzer.
   f. Close the lid manually; the analyzer will immediately start processing the test cartridge.
   g. After the timed testing process, the analyzer will display a result on the screen with either a Pass or Fail icon in the top right corner.
      i. Acceptability can also be confirmed by checking the result against the QC ranges in the package insert.
   h. Touch the accept icon to open the lid automatically.
   i. Remove the used test cartridge from the cartridge chamber and discard it in a JHMI-approved waste container.
   j. Repeat steps 3a through 4i for the second level of control.
   k. Manually close the lid.
      i. NOTE: Keep the lid closed at all times when the analyzer is not in use to protect the cartridge chamber.
   l. Immediately return the control vials back to the refrigerator after use.

C. If results fall outside the acceptable range, the Fail icon will appear, and the following QC corrective action must be taken:
   1. Verify QC and test cartridges are within the open expiration date and that they have been properly stored.
   2. Repeat test using a new Test Cartridge from the same box, and the same QC vial, taking care to ensure proper technique.
   3. If the repeat falls within the acceptable range, continue with patient testing.
   4. If the QC fails a second time, open a new bottle(s) of QC solution. Repeat test.
   5. If the QC fails a third time, open a new box of test cartridges. Repeat test.
   6. If the QC fails with the new QC solutions and test cartridges, DO NOT PERFORM ANY PATIENT TESTING. Contact the POCT office by calling 410-955-2645, by emailing POCTGroup@exchange.johnshopkins.edu, or by sending a CORUS message to "POCT Consult".
D. QC Documentation:
   1. Any Afinion™ analyzers, regardless of model, that are in use without utilizing connectivity require the completion and maintenance of paper QC logs. Refer to Appendix A.

X. PATIENT TEST PROCEDURE

Patient testing can be performed at any point, unless the icon is present. If this symbol is in the upper right-hand corner of the home screen, QC testing must be completed prior to patient testing.

A. Prepare for the test:
   1. Ensure the Afinion™ HbA1c Test Kit is at room temperature and is not expired.
   2. The operator must positively confirm the identity of the patient using two identifiers, neither of which may be the room number, prior to continuing with the fingerstick.
   3. Put on gloves.

B. Set up the patient test on the analyzer:
   1. Scan your JHED ID at the prompt for Operator ID, then select the Enter icon.
   2. Select the red patient sample mode icon. The lid will open automatically and the screen will prompt you to "Insert cartridge".
      a. NOTE: On the Afinion™ AS100 analyzer, the lid opens in an upwards fashion.
      b. NOTE: On the Afinion™ 2 analyzer, the lid opens by sliding outward.
   3. Touch the patient ID icon, then scan the patient's armband or label to assign the patient's CSN to the test being performed.
      a. NOTE: Confirm entry of the correct patient CSN by double checking the entry on the screen prior to selecting the Enter icon.

C. Perform the patient test:
   1. Open a test cartridge and remove it from the foil pouch by the handle, then set upright on the countertop.
      a. NOTE: The test cartridge must be used within 10 minutes.
   2. Perform a fingerstick on the patient using a safety lancet to collect a sample using the test cartridge sampling device by following the steps in Section VI: Specimen Collection and Handling.
      a. NOTE: Avoid air bubbles and excess sample on the outside of the capillary.
   3. Immediately and carefully replace the sampling device into the test cartridge.
      a. NOTE: Once the capillary is filled, analysis of the test cartridge must start within 1 minute.
      b. NOTE: If the Test Cartridge is accidentally dropped after filling the capillary tube, discard the test cartridge and repeat specimen collection.
   4. Insert the test cartridge with the barcode label facing left into the cartridge chamber of the analyzer.
   5. Close the lid manually and the analyzer will immediately start processing the test cartridge.
   6. After the timed testing process, the analyzer will display a result on the screen.
   7. Touch the accept icon to open the lid automatically.
   8. Remove the used test cartridge from the cartridge chamber and discard in a JHMI-approved waste container.
9. Manually close the lid.
    1. NOTE: Keep the lid closed at all times when the analyzer is not in use to protect the cartridge chamber.

XI. REFERENCE RANGES
Reference Range:

<5.7 % HbA1c

XII. REPORTABLE RANGE
A. For both the Afinion™ AS100 and Afinion™ 2 analyzers, the HbA1c reportable range is 4.0% - 15.0% HbA1c.
    1. The HbA1c results are displayed in 0.1% intervals.
    2. Reliable HbA1c results are produced within a hemoglobin range of 6 - 20 g/dL.

XIII. RESULTS INTERPRETATION
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) level.

Afinion™ HbA1c meets the performance standards established by NGSP.

A. Each individual test result must be interpreted with careful consideration to the patient’s medical history, clinical examination, and other laboratory results.
B. If the test result is questionable or if clinical signs and symptoms appear inconsistent with the test results, analyze the Afinion™ HbA1c controls and retest the specimen or send a sample to the Core Lab for analysis.

XIV. DOCUMENTATION
For all Afinion™ AS100 and Afinion™ 2 analyzers utilizing connectivity, patient results will automatically transmit to the electronic medical record, provided no error in data entry has been made.

The results will display under the "Labs" tab in Epic as "Hemoglobin A1c, Point of Care".

All results from analyzers not utilizing the connectivity module will require manual entry into the patient's electronic medical record, using order POC4.

XV. LIMITATIONS
For both the Afinion™ AS100 and Afinion™ 2 analyzers:

A. Do not analyze diluted, hemolyzed, or coagulated samples. An error message will appear if the analyzer detects a suboptimal sample.
B. Do not use cold test cartridges. An error message will appear at the onset of testing if the analyzer detects a test cartridge that is outside of the acceptable temperature range.
C. The test cartridge must be used within 10 minutes of opening the foil pouch.
D. Place the test cartridge in the analyzer within one (1) minute of filling the capillary tube with sample material.
E. Do not use test cartridges that have been accidently dropped on the floor or lab bench after specimen collection.
XVI. PROCEDURAL NOTES

A. Use fingertips only to operate the touch screen. Do not use pens or other sharp objects that may scratch or damage the screen.

B. The lid opens automatically, but must be closed manually. Do not try to open the lid manually.

C. Each foil pouch contains a dessicant bag; do not use the test cartridge if the dessicant bag is damaged and dessicant particles are found on the test cartridge.
   1. The test cartridge must be used within 10 minutes of removal from the foil pouch.

D. Do not touch the test cartridge optical reading area (see Figure 1). Always handle the test cartridge by the handle.

E. Do not re-use any part of the test cartridge.

F. When refrigerated, bring test cartridges to an operating temperature of 18-30°C for at least 15 minutes before use.
   1. NOTE: Information code 210 will display, and the test stops if the test cartridge is too cold.

G. When the instrument is not in use, the power may be turned OFF without loss of stored results.

H. When the instrument is idle, the display will change to a screen saver. Press anywhere on the screen to continue with testing.

I. Do not move the analyzer when a test cartridge is being processed.

J. Press the power button before unplugging the analyzer, unless directed otherwise during troubleshooting.

K. Patient and control results are stored in the memory of the Afinion™ AS100 and Afinion™ 2 analyzers.
   1. The last 500 patients and 500 control results are saved in separate records. If the capacity is exceeded, the oldest results will be deleted first.
   2. All records for analyzers utilizing connectivity are stored in the Results Repository of the Point of Care middleware system.
      a. To view previous results on the analyzer:
         i. Touch the "Menu" icon to enter the Main Menu.
         ii. Touch the "Patient Records" or "Control Records" icon.
         iii. The last record of the sample type selected is displayed.
         iv. To view more results touch the "Up" or "Down" icons.

XVII. MAINTENANCE

Maintenance requirements and procedures are the same for both the Afinion™ AS100 and Afinion™ 2 analyzers.

Monthly and As Needed: Clean the cartridge chamber.

A. If materials or liquids are spilled in the cartridge chamber, cleaning must occur immediately.

B. Regular maintenance of the Afinion analyzers requires cleaning of the cartridge chamber every 30 days.
   1. Put on gloves.
   2. Touch to open the lid.
   3. Unplug the power supply.
   4. Wet a cotton-tipped swab with 3 drops of water or a hospital-approved disinfectant. Squeeze the swab to ensure no excess liquid is present.
   5. Carefully remove spills and particles from the cartridge chamber.
   6. Wipe away residual liquid from the cartridge chamber using a new, dry cotton-tipped swab.
   7. Manually close the lid.
   8. Plug in the power supply and power on the analyzer.
As Needed: Clean the outside of the analyzer.

A. The exterior of the analyzers must be kept clean and dust-free at all times:
   1. Put on gloves.
   2. Power down the analyzer by pressing the ON/OFF button.
      a. NOTE: When the power is turned off, a shut down procedure is initiated. The cartridge carriage will move to a
         safe position, during which time the display will remain active a few seconds.
   3. Clean the outside of the analyzer and the touch display with a clean, lint-free and non-abrasive cloth dampened in
      water.
   4. To disinfect the exterior of the analyzer, use a hospital-approved disinfectant wipe.
   5. Allow the analyzer to air dry before powering back on.

XVIII. TROUBLESHOOTING

The Afinion analyzers utilize built-in failsafe mechanisms that assess individual processing steps during each test performed. If the failsafe mechanisms detect a problem, the test is terminated and an Information Code will be displayed on the touch screen.

When an information code appears on the screen, look up the possible cause from the table below or refer to the Operator's Guide, available on each unit, and take actions to solve the problem. Do not re-use a test cartridge that has been rejected by the analyzer. Once you have identified the information code and troubleshooting steps to take, touch ✅ to accept.

Common Information Codes are included in the table below. For a comprehensive list of information codes and troubleshooting, refer to the Operators' Guide.

<table>
<thead>
<tr>
<th>Code</th>
<th>Cause</th>
<th>Action to Take</th>
</tr>
</thead>
<tbody>
<tr>
<td>103</td>
<td>The hemoglobin concentration is below 6.0 g/dL</td>
<td>Repeat test with new sample and Test Cartridge. Repeat Code: hemoglobin outside range, no result reported. Send sample to Lab.</td>
</tr>
<tr>
<td>104</td>
<td>The hemoglobin concentration is above 20.0 g/dL</td>
<td>Repeat test with new sample and Test Cartridge. Repeat Code: hemoglobin outside range, no result reported. Send sample to Lab.</td>
</tr>
<tr>
<td>105</td>
<td>The HbA1c value is below 4.0%</td>
<td>Repeat test with new sample and Test Cartridge. Repeat Code: HbA1c is below the lower limit (4%). Report result as &quot;less than 4%&quot;.</td>
</tr>
<tr>
<td>106</td>
<td>The HbA1c value is above 15.0%</td>
<td>Repeat test with new sample and Test Cartridge. Repeat Code: HbA1c is above the upper limit (15%). Report result as &quot;greater than 15%&quot;.</td>
</tr>
<tr>
<td>201</td>
<td>Insufficient sample volume:</td>
<td>Repeat test with new sample and Test Cartridge. Ensure capillary is completely filled with no air bubbles.</td>
</tr>
</tbody>
</table>
   * Empty capillary
   * Air bubble in capillary
   * Capillary incompletely filled
### 202 Excess sample on the sampling device exterior
- Repeat test with new sample and Test Cartridge.
- Ensure only tip of capillary is in contact with sample.

### 204 Hemolyzed sample
- Repeat test with new sample and Test Cartridge.
- Repeat Code: send sample to Lab.

### Coagulated sample
- Repeat test with new sample and Test Cartridge.
- Ensure time from filling capillary until analyzing the Test Cartridge is as short as possible.

### Analyzer failure
- Repeat test with new sample and Test Cartridge. If problem persists, restart Analyzer and run Controls.

### 210 Test Cartridge is too cold
- Repeat test with new sample and new Test Cartridge within recommended operating temperature range.

### 302 Analyzer failure
- Restart the analyzer and run controls. Repeat the test with a new sample and test cartridge.

### 404 Operator ID is not found in operator list
- Contact unit trainer. Operator has not been added to authorized user list.

---

**In the event of multiple 300-level errors, the Point-of-Care Testing Office must be notified, in order to then communicate with the manufacturer.**

### XIX. DOWNTIME

**Instrument Downtime:**

- When the Afinion™ AS100 or Afinion™ 2 analyzer cannot be used for patient testing due to QC, calibration, or instrument failure and all troubleshooting steps have been performed, contact the POCT office at 410-955-2645, by emailing POCTGroup@exchange.johnshopkins.edu, or by sending a CORUS message to “POCT Consult”.
  1. If the testing unit does not have a back-up analyzer, send patient specimens to the Core laboratory.

**Epic and/or Telcor Downtime:**

- The Afinion™ AS100 and Afinion™ 2 analyzers may still be used for QC and patient testing.

**XX. OPERATOR TRAINING**

- Testing may be performed only by currently certified operators who have been trained by a Point-of-Care Coordinator, Nurse Educator, or designated unit trainer. Training records must be kept in the employee's personnel file and a copy sent to the Point-of-Care Testing office.

**Initial training must include:**

1. Review the policy online.
2. Successful performance of both levels of liquid quality control using the operators' unique JHED ID.
3. Completion of the initial competency assessment checklist (see Appendix C), to be kept in the employee's personnel file.
4. Passing score on the quiz following the MyLearning module.
XXI. OPERATOR COMPETENCY

In order to maintain ongoing competency and not become locked-out of the analyzer, all operators must successfully complete both levels of controls and the MyLearning module at least once each competency cycle.

The POCT Office competency cycle follows the fiscal year, running annually from 07/01 through 06/30.

XXII. REFERENCES


XXIII. SIGNATURES

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
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<tbody>
<tr>
<td>William Clarke</td>
<td>08/11/2022</td>
</tr>
<tr>
<td>Kimberly Peairs</td>
<td>08/10/2022</td>
</tr>
<tr>
<td>Sheela Magge</td>
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