

MOBILE DIABETES CENTER POLICY AND PROCEDURE

**SUBJECT: HEMOGLOBIN A1C SCREENING USING THE AFINION AS100 ANALYZER
INSTRUMENT– STUDENT/FACULTY/HEALTHCARE PERSONNEL**

EFFECTIVE DATE: 5/12

REVIEWED/REVISED DATE: 2/13, 7/14, 7/15, 1/16, 1/17, 3/18

PURPOSE: To provide non-diagnostic HbA1c screening in the community

MAY BE IMPLEMENTED BY: trained healthcare personnel and student.

Responsibilities:

- a. Hemoglobin A1c screening performed using the Afinion AS100 Analyzer machine by trained personnel is intended to provide a rapid non-diagnostic, HbA1c screening result that identifies whether a HbA1c level is within the expected range, or impaired. HbA1c screening will only be offered to people previously diagnosed with diabetes. A training video is available at: <https://www.youtube.com/watch?v=J2sLzbDZXYk>
- b. Non-diagnostic Hemoglobin A1c screening associated with the Mobile Diabetes Center will be done by healthcare personnel and students trained in the proper use of the Alere Afinion AS100 Analyzer Instrument.

PROCEDURE:

1. A greeter will be assigned to welcome screening participants, explain and obtain consent and assist participants in filling out screening questionnaire. (see Screening Procedures Policy) HbA1c screening will only be offered to people previously diagnosed with diabetes. The consent form will remain with the participant throughout the screening process.
2. Place the Afinion AS100 Analyzer on a dry, clean, stable and horizontal surface. Make sure that the Analyzer is located with sufficient surrounding airspace, at least 5 inches on each side. Acclimate the Analyzer to ambient operating temperature (15-32°C, 59-89° F) before use. Allow 15-20 minutes for acclimation.

3. Connect the power cable to the power cord adapter. Insert the plug from the power cord adapter into the power socket in the back of the Analyzer. Plug in the power cord to an outlet.
4. Switch on the Analyzer by pressing the ON/OFF button. An automatic Start-up procedure will be initiated. Please wait while the self test runs. This takes approximately 4 minutes. The Analyzer is ready for use when the start up menu is displayed on the screen and the green indicator light turns on.
5. The temperature displayed in the Start-up menu is the operating analyzer temperature. Make sure that the operating temperature is within the recommended range for the Afinion test.

Operating Precautions

When operating the Analyzer:

- Use fingertips to operate touch screen.
- Do not use pens or other sharp objects that may scratch or damage the screen. The lid opens automatically, but must be closed manually.
- **DO NOT** try to open lid manually.
- Empty the cartridge chamber and keep the lid closed when analyzer is not in use.
- Do not move the Analyzer when a Test Cartridge is being processed.

When handling the Test Cartridge:

- Do not use Test Cartridges after the expiration date, or if the Test Cartridges have not been stored in accordance with the recommendations
- Do not use the Test Cartridge if the foil pouch, the desiccant bag or the Test Cartridge itself is damaged.
- The Test Cartridges must reach recommended operating temperature prior to use.
- Do not open the foil package until just before use. Once opened, the Test Cartridge has limited stability.
- Handle and dispose the Test Cartridges and sample collection equipment as potential biohazardous materials. Use personal protective equipment.

Consult the Afinion Quick Guide for information regarding testing patient samples or controls.

<http://www.afinion.net/sites/default/files/publications/US%20quick%20guide%20no%20print%20lines.pdf>

Refer to the Afinion AS100 Analyzer User Manual for complete instructional materials related to operation of the Analyzer and Test Cartridges.

6. Prior to screening any participant, complete the control process.

Control Testing

7. A Faculty/Student/Healthcare Personnel will run a Quality Control Test on every machine:
 - Every time the Mobile Diabetes Center is in use.
 - With each new shipment of HbA1c kits
 - With each new lot of HbA1c kits
 - At least every 30 days
 - When training new users
 - Anytime an unexpected result is obtained
8. Allow the control to reach room temperature before use. This takes about 30 minutes.
9. Apply gloves any time in contact with A1C control solution or body fluids
10. Mix the control well by thoroughly shaking the vial for 30 seconds
11. Inspect the vial to ensure that the control solution is homogenous
12. Remove the sampling device from the Test Cartridge. (Use the handle to keep the Test Cartridge steady against the table or counter and pull the sampling device straight up)
13. Fill the capillary; hold the sampling device close to horizontal and bring the tip of the capillary tube into contact with the surface of the control solution. Make sure that the capillary tube fills completely. It is not possible to overfill. DO NOT wipe off the capillary. (Avoid air bubbles and getting excess sample on the outside of the capillary)
14. Immediately and carefully replace the sampling device into the Test Cartridge.

15. Touch the Control Mode icon on the Analyzer display screen. The lid opens automatically.
16. Touch the Control ID icon on the Analyzer display screen. Enter the Control ID number. Touch the Enter icon to confirm. The control test will take about 3 minutes to process.
17. ****RETURN CONTROL SOLUTIONS TO REFRIGERATOR****
18. Result will appear on the Analyzer screen. Compare the test results with the values listed on the front page of the HbA1c Control Package Insert
19. Record the Control Test result, and then touch the Accept icon. (The lid opens automatically. The result will be saved in the control records)
20. Remove the used Test Cartridge from the cartridge chamber and discard it in a Red Bio Hazard bag. Close the lid manually.

Participant Screening:

21. Open the foil pouch. Grip the handle and remove the Test Cartridge from the pouch. Check the expiration and discard dates on the Test Cartridge packaging. Set the Test Cartridge upright on a clean, level surface. Discard the desiccant bag and foil pouch in suitable waste container. *(Once opened the Test Cartridge has limited stability)*
22. Inspect the Test Cartridge. Do not use the Test Cartridge if it is damaged or if loose desiccant are found on the Test Cartridge. *(Use the handle to avoid touching the optical reading areas)*
23. Do not allow the barcode label to become wet, dirty or scratched.
24. A Faculty/Student/healthcare personnel will obtain a blood specimen for screening purposes and understand how to correctly use lancing device and capillary. Refer to the Afinion AS100 Analyzer User Manual for all instructional materials.
 - a. Wash or sanitize hands
 - b. Put on gloves
 - c. Cleanse the finger using alcohol. Allow the area to air dry
 - d. Using lancing device firmly puncture chosen site
 - e. Place Lancing device into sharps container
 - f. Allow a good drop of blood to form prior to sampling

25. Remove the sampling device from the Test Cartridge. *(Use the handle to keep the Test Cartridge steady against the table or counter and pull the sampling device straight up)*
26. Fill the capillary; hold the sampling device close to horizontal and bring the tip of the capillary tube into contact with the surface of the sample. Make sure that the capillary tube fills completely. It is not possible to overfill. DO NOT wipe off the capillary. *(Avoid air bubbles and getting excess sample on the outside of the capillary)*
27. Apply direct pressure to the wound site with a clean gauze pad.
28. Immediately and carefully replace the sampling device into the Test Cartridge. *(The time from filling the capillary until analyzing the Test Cartridge should be as short as possible; one minute or less)*
29. Touch the patient sample mode icon on the Analyzer display screen. The lid opens automatically.
30. Insert the Test Cartridge with the barcode label facing left.
31. Close the lid manually. The Analyzer will start processing the Test Cartridge. The test will take approximately three minutes.
32. Place gauze, alcohol wipe, gloves and other trash into trash bag.
33. The test result will appear on the screen. Record the result on the patient's consent, and give to the patient in verbal and written format.
34. Touch the green check mark icon on the screen to accept the result. The lid will open automatically.
35. Remove and discard the Test Cartridge in an appropriate Red Bio Hazard bag.
36. Close the lid manually. *(Keep the lid closed to protect the cartridge chamber when the Analyzer is not in use)*
37. Appropriate education will be shared with the participant based on the screening results by the lead RN. Participants will be told that screening results are in no way diagnostic of any disease. Education provided to clients and student projects will be based on the American Association of Diabetes Educators best practice guidelines.
38. Glycemic targets should be individualized for each person with diabetes. (AADE, 2011) Participants with an HbA1c screening result that is elevated above their target range should be referred to their primary provider for follow-up. All participants with an

HbA1c result that is above their stated target or above 7% should be referred to their primary provider.

39. Faculty, students and healthcare personnel will refer each person with an unexpected screening result to his or her primary provider. If a person does not have a primary provider, assistance in locating/identifying a provider will be offered. If a person does not have a provider and does not have insurance he or she will be referred to a clinic such as Charles Drew, One World, Planned Parenthood or the Renaissance Health Clinic.
40. Faculty and students will immediately direct persons with symptoms of hypoglycemia or hyperglycemia to the nearest Emergency Department or in the case of severe symptoms activate the Emergency Response System by calling 911.

References

Afinion HbA1c Quick Guide, retrieved February 25, 2013 from,

<http://www.alere.com/en/home/product-details/afinion-as100-analyzer-us.html>

American Association of Diabetes Educators [AADE], (2011), *The Art and Science of Diabetes*

Self-Management Education Desk Reference. 2nd Ed. Chicago, Illinois.

Axis-Shield Inc. (n.d.) *Afinion AS100 Analyzer User Manual*, REF 1115175. Oslo, Norway.