Issues Related to the use of the A1C with Screening And/or Diagnosis of Diabetes

American Diabetes Association (ADA) Criteria for Diagnosis of Diabetes

1. Fasting plasma glucose (FPG) ≥ 126 mg/Dl. Fasting is defined as no caloric intake for at least eight hours* **OR**
2. 2-hour plasma glucose (PG) ≥ 200 mg/dL during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75- g anhydrous glucose dissolved in water*. OR
3. A1C ≥ 6.5%. This test should be performed in a laboratory using a method that is National Glycohemoglobin Standardized Program (NGSP) certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay. * **OR**
4. **In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).**
   ** In the absence of unequivocal hyperglycemia, diagnosis requires two abnormal test results from the same sample or in two separate test samples.*

ADA Criteria for Determining Prediabetes*

1. Fasting plasma glucose of 100-125 mg/dL (impaired fasting glucose)
   OR
2. 2-hour plasma glucose during 75-g OGTT 140 to 199 mg/dL (impaired glucose tolerance)
   OR
3. A1C of 5.7% – 6.4%
   ***** For al three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at the higher end of the range.

Important Points is the use of the A1C Assay in diagnosing diabetes:

- A1C testing for **diagnostic** purposes should be performed in a laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP) certified or traceable to the Diabetes Control and Complications Trial (DCCT).
- Although Point-of-care A1C Assays May be NGSP certified or U.S. Food and Drug Administration approved for diagnosis, proficiency testing is not always mandated for performing the test. Therefore, point of care assays approved for diagnostic purposes should only be considered in settings licensed to perform moderate to high complexity tests.
- Be alert to the impact of hemoglobin variants on A1C values. There are certain situations where A1C would not be accurate and should not be used, such as hemolytic anemia, Thalassemia, recent blood transfusion, or severe bleeding.

Source: American Diabetes Association, Clinical Practice Recommendations, 2019

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Wisconsin WISEWOMAN Program Policies for Using the A1C Test

1. WISEWOMAN screening programs may use the A1C test to diagnose diabetes if they draw blood at the Integrated Office Visit (IOV) and send it to a central NGSP certified lab for analysis. Diagnosis must be confirmed by drawing a second sample on a different day during a Diagnostic Office Visit (DOV) and by following the same protocol of sending it to a central NGSP certified lab for analysis.
2. WISEWOMAN screening programs that identify a client at **high risk** for diabetes using an A1C **point-of-care test cannot** establish a diagnosis of diabetes for the client using that test. The program must refer the client for additional central laboratory tests before confirming a diagnosis of diabetes.
3. The WISEWOMAN Program approves use of the A1C point-of-care test for two scenarios:
    a. To assess long term diabetes management in a client known to have diabetes **OR**
    b. To identify a client who is at **high risk** for diabetes (pre-diabetes) however
        i. Additional central laboratory tests must be done to confirm the diagnosis; this would typically be done through referral due to the limitations of the WISEWOMAN program.
        ii. The A1C **point-of-care test cannot** be used to establish a diagnosis.