

D0411 – ADA Guide to Point of Care Diabetes Testing and Reporting

Developed by the ADA, this guide is published to educate dentists and others in the dental community on this procedure and its code first published in *CDT 2018* and effective January 1, 2018.

Introduction

Simple chair-side screening for dysglycemia via finger-stick random capillary HbA1c glucose testing can be used to rapidly identify high-risk patients. Chair-side screening and appropriate referral may improve diagnosis of pre-diabetes and diabetes.

A code for the finger-stick capillary HbA1c glucose test procedure can foster its broader adoption. This test is relevant to dentists as diabetes is a risk factor related to periodontal disease. It is akin to caries risk testing that relates to tooth decay and remedial restorative procedures and preventive procedures. Hb1Ac testing enables a dentist to amend the patient's treatment planning depending on whether the results are the first indicator of a new diabetic condition, or if the results indicate a change in the existing diabetic condition.

The full CDT Code entry (Nomenclature only; no Descriptor):

D0411 HbA1c in-office point of service testing

The following pages contain a number of Questions and Answers, all intended to provide readers with insight and understanding of the procedure and its reporting, including points to consider before offering this service to your patients.

Questions and Answers

1. What is HbA1c?

Hemoglobin A1c, also known as glycated hemoglobin, is a measure of the amount of glucose attached to red blood cells and directly relates to the average blood glucose levels. Patient fasting is not required prior to an HbA1c test.

2. When should I suggest that a patient receive an HbA1c Point of Care Test (POCT)?

There are a number of factors that could place a patient at risk of diabetes, some of which may already be in their dental records, and include:

- Obesity or being overweight
- Ethnic background (diabetes happens more often in Hispanic/Latino Americans, African-Americans, Native Americans, Asian-Americans, Pacific Islanders, and Alaska natives)
- Sedentary lifestyle (exercise less than three times a week)
- Family history (parent or sibling who has diabetes)

A resource that will help identify patients who might be candidates for the D0411 procedure is the [Point-of-care prediabetes identification](#) (click on hyperlink to open) guide prepared jointly by the American Diabetes Association, the American Medical Association, and the Centers for Disease Control.

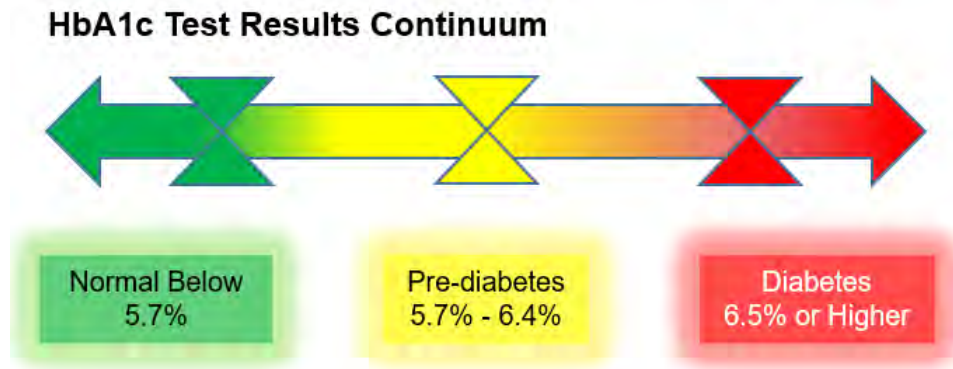
3. How is the procedure delivered?

There are established protocols for acquiring and assaying the small sample of blood for POCT to measure HbA1c. Protocol steps include: a) finger selection; b) massaging, cleaning and drying the site; c) skin puncture with a lancet; d) wiping away the first blood before collecting the sample without “milking the finger” site; e) placing the sample into the analyzing device; and f) reading the results.

Every blood donor has experienced skin puncture with a lancet. There can be some variations in steps e) and f), dependent on the test kit used.

4. What do the analysis results indicate?

The HbA1c analyzing device displays a percent figure. There is a recognized range of percentages that is used to indicate whether the patient is considered normal, pre-diabetic or diabetic, as illustrated:



5. What should I do if my patient’s HbA1c test result is at the pre-diabetes or diabetes percentage?

A dentist should assess how this information affects the patients current and future treatment plans. In addition to informing the patient of the outcome, it would be appropriate to recommend they contact their physician for a definitive diagnosis. A third action would be to determine whether the patient’s dental benefit plan provides coverage for additional prophylaxis procedures, if indicated.

6. How would the procedure’s findings help my treatment planning for the tested patient?

The screening result could lead to a definitive diagnosis of diabetes by a physician. A diagnosis of diabetes may indicate that the patient could benefit from more frequent prophylaxes than a person without such a diagnosis to maintain their oral health. Some dental benefit plans cover “extra” prophylaxis procedures for patients with diabetes.

7. Are there rules or regulations regarding in office HbA1c testing, documented with CDT Code D0411?

Yes, be sure to check your state’s Dental Practice Act to determine if testing is within the scope of your license. There are also federal, and state, regulations concerning laboratories that may affect your business decision to provide this service.

8. What federal or state regulatory requirements must I satisfy before offering this procedure to my patients?

There is an overarching federal regulation – Clinical Laboratory Improvement Amendments of 1988 (CLIA). Any dental practice that performs tests on human tissues, including blood, is considered a laboratory according to CLIA. This means that the practice requires certification by the state and the Centers for Medicare and Medicaid Services (CMS) before collecting and testing the blood sample.

The “finger-stick” point of service test considered to be of low complexity by the Food and Drug Administration (FDA), and is in the “waived” category of laboratory procedures. This means that CMS will issue two-year Certificate of Waiver (COW) to a dental office that performs this test. The COW fee is \$150, and the dental office must perform only the waived test following the manufacturer’s current instructions without changes. A COW holder is subject to announced or unannounced on-site inspections by CMS.

Federal regulations establish the requirements threshold. Local or state laws may be more stringent – there may be specific regulations concerning practice personnel who may administer the test; biohazard safety, including handling and disposing of medical waste.

For example, New Jersey’s State Board of Dentistry ruled that it is within the scope of practice for New Jersey licensed dentists to perform in-office A1C diabetes screening tests for at-risk patients. The board noted that: a) such testing is not presumed to be the standard of care; and b) for A1C screenings beyond the normal range, dentists should refer patients to a physician for a formal evaluation, diagnosis, and treatment.

The following chart illustrates how a dental practice would be considered a laboratory under CLIA, and the applicable federal regulations. A red arrow points to where the D0411 procedure falls (Simple or Waived Tests), indicating that the dental practice is required to have the \$150 two-year COW.

CLIA Flowchart

Is your dental practice considered a laboratory under CLIA?

Do you utilize human tissue samples or specimens at your office?
(i.e., saliva, blood, plaque, hard or soft tissue biopsy)

No. We do not and never have.

You are probably not a laboratory. If you do not take or send out samples, you are likely not affected by CLIA.

Yes, but we only take the samples in office, and send them to an outside lab for testing.

You are probably not a laboratory. If you use an outside laboratory to get results, that facility is a laboratory and you should check the CLIA registry online to guarantee that the laboratory is certified and follows federal, state and local law.

Yes. We perform tests to diagnose, prevent, treat, and assess patient health.

You are most likely a laboratory. Next, look at the FDA categories of test complexities to see what level(s) apply to you.

Local and state laws may override CLIA – check with your attorney. Your state dental association may also have information.

Simple or Waived Tests (i.e., blood glucose, cholesterol)
If the test is a simple laboratory procedure with an insignificant risk of erroneous results, you may be eligible for a certificate of waiver after your laboratory has been certified through the CLIA process. See the FDA website for a complete list of tests that have been waived. "Waived" does not mean you don't have to do anything; you still need to obtain certification, follow the manufacturer's instructions for test performance, and maintain the appropriate records.

Moderate Complexity/PPM (e.g., INRatio2 device or microscopic examinations)
If the test is of moderate complexity or is a provider-performed microscopy procedure, you may be eligible for a Certificate for PPM. You need to apply to the CLIA program and designate the applicable waiver. See five types of certificates and CLIA enrollment.

High complexity
See the FDA website for more information.

The information given is neither intended to, nor does it, provide either legal or professional advice. Dentists and others should consult directly with a qualified attorney or professional for appropriate legal or professional advice. ADA makes no representations or warranties of any kind about the completeness, accuracy, or any other quality of the information in the above piece. Nor does the ADA make any representations or warranties about the information provided at non-ADA websites, which the ADA does not control in any way.

This information was developed by the Council on Dental Practice.
©2011 American Dental Association. All rights reserved.

9. What are a dentist's ethical obligations to deliver this procedure to patients (e.g., all patients; those presenting with signs or symptoms or medical history)?

Within dentistry there is no consensus that HbA1c screening is considered a standard of care. In fact the New Jersey State Board of Dentistry has explicitly stated that this screening is not presumed to be a standard of care.

From another perspective, the American Diabetes Association has published its *Standards of Medical Care in Diabetes 2016*, which addresses HbA1c testing. Links to this information, and others pertaining to diabetes, dentistry and oral health are published on the American Dental Association's web site – <http://www.ada.org/en/member-center/oral-health-topics/diabetes>

A dentist should provide a patient with sufficient information about the procedure, including its relevance to both oral and general health, so that she or he can make an informed decision.

10. How do I close the referral loop – informing the patient's physician – of the finger-stick findings?

If the HbA1c screening is delivered the findings should be conveyed to the patient's physician or appropriate health care provider. Before doing so be sure to have an information release form signed by the patient on file. These referrals must be tracked and documented. Failure to do so may lead to liability issues.

11. What should I do with the results if the patient does not have a physician or other health care provider who can act on the information?

The patient should be informed of the screening's findings, be directed towards resources containing more information, and encouraged to become a physician's patient of record for their other health needs. These actions must be noted in the patient's dental records.

12. What is the likelihood of false measures since this is a screening type procedure and not a full lab test?

The likelihood of false results is considered extremely low. This and the test's simplicity are factors that led the FDA to place this type of test into the "waived" category of laboratory procedures. They are also reasons why test kits are sold over-the-counter to individuals who wish to self-monitor.

13. What are the additional overhead costs and ongoing administrative activities that must be in place in order to offer this screening service?

Before incorporating HbA1c screening a dental practice should consider factors that contribute to total cost. These include personnel time, consumable products and durable goods, additional training of personnel, additional safety and biohazard supplies, record keeping associated with good laboratory practices and the maintenance and storage of these records, certification fees, counseling and education of patients, and referral/tracking of referrals of patients.

14. What components of the D0411 procedure may be delegated to staff and which may only be performed by the dentist

As with any procedure, the practitioner providing the service is determined by state law and licensure. Direct or indirect supervision by a dentist may, or may not, be a requirement.

15. What documentation should I maintain in my patient records, and what will be needed on a claim submission when reporting D0411?

The patient's records would include the same information about services provided as is done with other dental procedures – plus notations of the activities described in the answers to questions 4, 9 and 10 above, as applicable.

A dental claim would be coded and completed in the same manner as other dental procedures (e.g., date of service, CDT Code, full fee).

16. What dental benefit plan coverage – commercial or governmental – is anticipated?

As with any procedure documented with a CDT Code there is no guarantee of coverage by a patient's dental benefit plan. At least one third-party payer, Delta Dental of New Jersey, is promoting delivery of HbA1c screening by its network dentists for their patients.

17. What factors should I consider when determining my full fee for the D0411 service?

Dentists and other practitioners in the dental community acquire their skills and expertise through training and experience. It is up to each individual to determine the value of their time and the time required to provide the service when determining their full fee. Other unique factors such as the cost of acquiring and maintaining a supply of the finger-stick test materials may also be considered.

Questions or Assistance?

Call 800-621-8099 or send an email to dentalcode@ada.org

Notes:

- This document includes content from the ADA publication – *Current Dental Terminology (CDT)* ©2017 American Dental Association (ADA). All rights reserved.
- Version History

Date	Version	Remarks – Change Summary
07/17/2017	1	Initial publication