

COVID-19 & Lab Testing Requirements Toolkit

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Overview

Welcome to the COVID-19 & Lab Testing Requirements Toolkit. The American Dental Association, in consultation with the ADA's Advisory Task Force on Dental Practice Recovery, has developed this suite of resources to help guide dentists interested in offering their patients rapid response, point of care COVID-19 testing within the practice.

The information and messaging contained in this resource is intended to guide you through the process of applying for the federal certification required in order to offer this type of testing. It also offers useful information that will help your staff educate patients about this important, and timely, value-added service available through your practice.

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Disclaimer. These materials are intended to provide helpful information to dentists and dental team members. They are in no way a substitute for actual professional advice based upon your unique facts and circumstances. ***This content is not intended or offered, nor should it be taken, as legal or other professional advice.*** You should always consult with your own professional advisors (e.g. attorney, accountant, insurance carrier). To the extent ADA has included links to any third party website(s), ADA intends no endorsement of their content and implies no affiliation with the organizations that provide their content. Further, ADA makes no representations or warranties about the information provided on those sites.

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In Office Testing and CLIA

Knowing and adhering to industry best practices can help ensure test reliability and quality patient care.



What is CLIA?

CLIA stands for the Clinical Laboratory Improvement Amendments. It is a federal law that establishes quality standards for all laboratory testing to ensure accuracy, reliability, and timeliness of patient test results regardless of where the test was performed.



Who is Affected?

All laboratories must comply with federal CLIA regulations which broadly define a laboratory as including any facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of human beings, or the assessment of their health. Even if a facility only performs one test for these purposes, or performs the test at no charge to the patient, it qualifies within the definition of a laboratory.



Why Should I Be Concerned?

Any dental practice that performs tests on human tissue (including saliva, plaque, blood or hard or soft tissue) must comply with CLIA regulations. Practices that match the definition of a laboratory must obtain the certificate that appropriately corresponds to the complexity of the tests performed.



What Types of Tests Used for COVID-19 Could Apply to My Practice?

Tests for COVID-19 have received Emergency Use Authorization from the U.S. Food and Drug Administration (FDA). While most tests are performed in moderate or high complexity laboratories, “waived” tests are typically simple procedures and laboratory examinations that have a low risk for error. Be sure to consult [the current list of COVID-19 tests that have been authorized for emergency use](#) to determine the level of certification needed for particular tests.

- COVID-19 antigen tests are tests that can be used to detect the presence of the COVID-19 virus.
- COVID-19 antibody tests are blood tests that can detect if a person has antibodies to SARS-CoV-2, the virus that causes COVID-19 and can help identify people who may have been infected with the SARS-CoV-2 virus or have recovered from the COVID-19 infection.

The accuracy of any particular test is critical and is measured in terms of both sensitivity and specificity:

- Sensitivity measures the test’s ability to identify persons who actually have the disease (true positives).
- Specificity measures the test’s ability to correctly identify persons without disease (true negatives).

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The FDA will not consider a test for EUA unless Sensitivity is > 95%, and Specificity is > 98% with a lower bound of the two-sided 95% confidence interval > 95%.

Another type of test, the Polymerase Chain Reaction (PCR) test, can be conducted by collecting nasopharyngeal specimens, throat swabs, nasal swab specimen, or collected saliva. Facilities offering this type of testing must be CLIA-certified for high and moderate complexity and cannot be offered by locations qualifying for certificates of waiver.

Additional information on testing requirements is available in the ADA's resources:

- [Diagnostic Testing Options for Sars-CoV-2](#)
- [Testing Dental Employees for Antibodies and Antigens](#)



How are Laboratory Tests Classified by the FDA?

The FDA divides laboratory tests into three categories based on their level of complexity. The more complicated the test, the more stringent the CMS requirements for certification. Test classifications are detailed in the table below. Labeling on each test will detail its category of classification.

Simple or Waived	Moderate Complexity, and Provider-Performed Microscopy (PPM)	High Complexity
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What PPE Should Be Worn When Collecting Testing Samples?

[CMS](#) recommends that providers collecting specimens or located within six feet of individuals suspected to be infected with SARS-CoV-2 should use the recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or a facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens. The appropriate infection control protocols should be followed at all times.



When Registered to Perform COVID-19 Testing, Will My Practice Be Required to Test Individuals Who Are Not Patients of Record?

At this point in time, the best answer is likely not. Private dental practices are not generally required to provide free care, testing or screening to the public. In addition, since private dental practices generally do not have to accept any patient that comes into the office, if COVID-19 testing is a protocol offered for your patients, then you likely would not be required to provide "on demand" testing for persons who do not have a history of being treated by you and your staff.

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The current expectation is that dental practices applying for CLIA certification would be offering that testing as part of an enhanced patient protocol rather than as tests for non-dental patients. However, it is important to recognize that norms and mandates are subject to change in response to the pandemic and that, since there is no precedent, it's impossible to predict what may be required by federal, state and local governments in the future.



Always Check Your Local and State Laws!

While making sure your facility is CLIA compliant, keep in mind that CLIA is the minimum required of all laboratories. Local and/or state laws that are more stringent may override the CLIA standards. This Toolkit includes an [interactive map](#) that details each state's requirements and contact information for the appropriate regulatory agency.

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Regulations by State ([map](#))

This [interactive map](#) offers details about laboratory testing requirements that may be in place in your state. Use it to find your state regulatory agency and any additional fees or testing requirements that may be in place in your state. In many states, only the federal CLIA requirements are mandated.

Clinical Laboratory Improvement Amendments (CLIA) Guidance for Dentists

This information was updated September 23, 2020.

To view the latest state-by-state updates on clinical laboratory improvement amendments, click a state or select a state from the dropdown filter.

Select a State
(All)

States with affirmative declarations regarding dentists administering COVID-19 tests

Guidance for Illinois

State Agency
Illinois Dept of Public Health

State Restrictions
The state of Illinois follows all Clinical Laboratory Improvement Amendments (CLIA) regulations for laboratory facility and personnel requirements. Illinois does not have any additional licensure and regulations.

State Fee for Certificate of Waiver
None

Federal Agency Regulations

Federal Fee for Certificate of Waiver
\$180/2 years

COVID-19 Information
Illinois Department of Public Health: "Dentists may choose to incorporate COVID-19 testing as outlined below into the provision of oral health care."

Sources for Illinois

State Agency Source
<http://dph.illinois.gov/topics-services/health-care-regulation/clia>

COVID-19 Source
<http://www.dph.illinois.gov/covid19/community-guidance/routine-oral-and-dental-care>



TIP: Select your state from the drop-down or use your cursor to select a state on the map (such as IL as shown) to learn more.

Applying for a Federal Certificate of Waiver

Some dentists have expressed interest in offering patients rapid response COVID-19 testing in their practices once reliable point of care testing is available at a level that makes it feasible for it to be used in individual dental practices. Two primary benefits of offering COVID-19 point of care diagnostic testing in the dental practice are that it makes it easy, and quick, for patients to be tested while also providing your staff with some reassurances about the health status of the patients they treat.



Dentists who are thinking about offering patients COVID-19 point of care diagnostic testing are encouraged to follow the steps outlined below.

- Become familiar with basic information about [Clinical Laboratory Improvement Amendments \(CLIA\)](#).
 - The Centers for Medicare & Medicaid Services (CMS), through the Clinical Laboratory Improvement Amendments (CLIA), regulates all (non-research) laboratory testing performed on humans in the U.S. and seeks to help ensure quality laboratory testing.
 - Review the agency's [Frequently Asked Questions \(FAQs\)](#), [CLIA Guidance During the COVID-19 Emergency](#), its [Research Testing and Clinical Laboratory Improvement Amendments of 1988 \(CLIA\) Regulations](#) and its [Direct Access Testing \(DAT\) and the Clinical Laboratory Improvement Amendments \(CLIA\) Regulations](#).
- Review [How to Apply for a CLIA Certificate, Including International Laboratories](#) and the [CLIA Certificate Fee Schedule](#). Most dental practices can expect to pay a biennial fee of approximately \$180.
- Complete [Application for a CLIA Certificate: FORM CMS-116](#).
 - While the 10-page application may at first seem overwhelming, the last five pages offer completion instructions and a lengthy listing of Tests Commonly Performed and Their Corresponding Laboratory Specialties/Subspecialties.
 - The agency advises applicants with questions about completing the form to contact the appropriate [Clinical Laboratory Improvement Amendments \(CLIA\) State Survey Agency Contacts](#).
 - Some states, such as California, have additional licensure requirements that must be fulfilled before submitting the FORM CMS-116; other states, such as Washington, have other requirements and should contact the appropriate state agency before completing the FORM CMS-116. Consult the [interactive state map](#) that's included in this Toolkit for details on your state's requirements.
- Information needed to complete the application includes:
 - **Section I: General information:** Whether this is a new application or a request to update an existing one, basic information regarding the name and location of the entity submitting the application and the federal taxpayer identification number.

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- Section II: Type of Certificate Requested: For most dental practices, this will likely be a request for a Certificate of Waiver. Since this type of application requires applicants to only complete Sections I – VI and IX – X, information on completing Sections VII and VIII will be skipped.
- Section III: Type of Laboratory: Applicants are advised to check the box in front of the facility type that best describes the practice. For most dentists, the selection will likely be Box 22 Practitioner Other (specify).
- Section IV: Hours of Laboratory Testing: Detail, for each day of the week; the hours during which testing will be performed.
- Section V: Multiple Sites: In this section, you will need to indicate whether the single application is intended to cover multiple testing locations. If so, the application will need to detail if it's a mobile unit, a not-for-profit or Federal, State or local government laboratory that conducts limited public health testing, or a hospital with multiple labs in contiguous buildings on the same campus.
- Section VI: Waived Testing: Most dental practices interested in offering point of care testing for COVID-19 will likely apply only for a Certificate of Waiver. ***Note that you will need to specify which waived testing will be performed as well as the estimated total annual test volume for all waived tests performed. While applicants are encouraged to be as specific as possible and to detail each analyte test system or device that will be used, it's important to respond in a manner that will enable the practice the flexibility to perform any COVID-19 point of care testing that may be allowed under the U.S. Food and Drug Administration's Emergency Use Authorization (EUA).***
- Section VII: PPM Testing and Section VIII: Non-Waived Testing: Most dental practices applying for the CLIA Application for Certification with Waiver can skip these two sections.
- Section IX: Type of Control: Applicants must select a response that describes the ownership status of the facility: most dental practices would likely qualify as Option 4: For Profit/Proprietary.
- Section X: Director Affiliation with Other Laboratories: Applicants are required to disclose whether they serve as director for other, separately certified, labs.

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CLIA Regulatory Compliance for Certificates of Waiver

Laboratories that only perform waived testing must:

- Enroll in the CLIA Program and obtain a Certificate of Waiver
- Pay applicable certificate fees every 2 years
- Follow manufacturer's test instructions for the test(s) performed
- Follow any additional requirements of your state
- Notify your State Agency of any changes in ownership, name, address or Laboratory Director within 30 days.

Laboratories with a Certificate of Waiver are not subject to a routine inspection (survey) under the CLIA Program, but may be surveyed in response to a complaint or if they are performing testing that is not waived.

Tips for Performing Waived Testing



Document testing staff has completed initial training by:

1. Reading and understanding manufacturer's directions regarding:
 - Intended use
 - Limitations of procedure
 - Recommended quality control procedures for each type of test
 - Storage and handling requirements of each type of test
 - Verification of expiration dates.
2. Following procedures to safely perform tests by:
 - Knowing what PPE should be worn when collecting patient samples
 - Understanding how to collect patient samples required by the test and how to label samples
 - Knowing how to safely dispose of biohazardous waste.
3. Completing patient reports so they are legible and timely.
4. Maintaining records of testing.
5. Maintaining equipment and maintenance logs, as required by test.
6. Documenting reporting of COVID-19 test results to appropriate public health agencies.

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COVID-19 Test Reporting Requirements

The federal Coronavirus Aid, Relief and Economic Security (CARES) Act requires every COVID-19 test site to report every diagnostic and screening test performed to the appropriate state or local public health departments. This includes all tests regardless of the results (whether positive or negative) and the type of test performed, such as PCR (polymerase chain reaction), antigen or antibody tests.

The reporting requirements for COVID-19 tests are intended to ensure:

1. the rapid and thorough public health response to the COVID 19 pandemic;
2. that testing data is both complete and comprehensive testing data; and
3. the provision of vital guidance for disease incidence trends and contact tracing activities.



What Is a Test Site?

COVID-19 diagnostic and screening testing sites include non-laboratory testing locations and other facilities or locations that offer point-of-care or in-home testing related to SARS-CoV-2 and are defined as:

- laboratories that perform clinical diagnostic or screening testing under the Clinical Laboratory Improvement Amendments (CLIA)
- non laboratory COVID-19 diagnostic or screening testing locations
- other locations or facilities offering COVID-19 point of care diagnostic or screening tests, such as dental offices
- in-home diagnostic or screening tests



How Are Test Results Reported?

Laboratory data must be reported directly to state or local public health departments according to state and/or local law or policy. Data must be sent via existing reporting channels to ensure rapid initiation of case investigations and concurrent reporting of results must be shared with ordering provider or patient, as applicable.

Dentists are encouraged to contact their state or local public health department for specific information on reporting requirements and the method for reporting. For specific COVID-19 inquiries by state, see the [National Association of County and City Health Officials: Local Health Department COVID-19 Directory](#).

Additional guidance is available through the U.S. Department of Health and Human Services' (HHS) [COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115](#)

Electronic reporting options are available to reduce the burden on providers reporting test results. Laboratories that are not currently reporting electronically to their state or local health department and want assistance in establishing electronic reporting can contact CDC's [Emergency Operations Center, Laboratory Reporting Working Group](#).

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What Must Be Reported?

The results of **each** COVID-19 test performed **must** be reported to the appropriate state or local public health department on a daily basis and within 24 hours of when results are known. Both negative and positive test results must be reported. According to guidance issued by HHS:

"These data contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities."

While more details on the reporting requirements are outlined in an [HHS FAQ document](#) and on the website of the [U.S. Centers for Disease Control and Prevention](#) (CDC) state and jurisdictional health departments require that complete laboratory data should include these data elements:

1. Test ordered — [LOINC codes provided by CDC](#)
2. Device Identifier
3. Test result — use appropriate LOINC codes and SNOMED codes, [provided by CDC](#)
4. Test Result date (date format)
5. Accession # / Specimen ID
6. Patient age
7. Patient race
8. Patient ethnicity
9. Patient sex
10. Patient residence zip code
11. Patient residence, county
12. Ordering provider name and NPI (as applicable)
13. Ordering provider zip
14. Performing facility name and CLIA number
15. Performing facility zip code
16. Specimen Source — codes provided by CDC
17. Date test ordered (date format)
18. Date specimen collected (date format)

In addition, the following demographic data elements should also be collected and reported to state or local public health departments:

1. Patient name (Last name, First name, Middle Initial)
2. Patient street address
3. Patient phone number with area code
4. Patient date of birth
5. Ordering provider address
6. Ordering provider phone number

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Dental office that are performing point of care testing should contact their state or local health departments for assistance regarding the preferred reporting format and secure information exchange portal to protect patient privacy. The format may vary by jurisdiction but CSV (Comma Separated Values) format is a common plain text format in which values are separated by commas, and allows data to be saved in a tabular format that is easily read in many different software systems. CSV format is used to export a high volume of data and is used to organize and save large amounts of imported data.

The following [reporting form](#) is one example of how testing data may be formatted:

REPORTING FORM	
Patient Name	
Patient Address	
Patient Phone Number with Area Code	
Patient Date of Birth	
Dentist Address	
Dentist Phone Number	
Test Performed – use harmonized LOINC codes provided by CDC	
Device Identifier	
Test result – use appropriate LOINC and SNOMED codes	
Test result date	
Accession number/Specimen ID	
Patient age	
Patient race	
Patient ethnicity	
Patient sex	
Patient residence zip code	
Patient residence county	
Ordering provider name and NPI (as applicable)	
Ordering provider zip code	
Performing facility name and/or CLIA number	
Performing facility zip code	
Specimen source – use appropriate LOINC, SNOMED-CT, or SPM codes, or equivalently detailed alternative codes	
Date test ordered	
Date specimen collected	

State and jurisdictional health departments will forward deidentified data to the CDC so the agency can use that information to assess COVID-19's impact, positivity trends, testing coverage, etc. The information can also be used to help identify supply chain issues for reagents and other materials.

Testing sites that experience issues with diagnostic test products are urged to report the problem via the U.S. Food and Drug Administration's [MedWatch Voluntary Reporting Form](#).

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FAQs for Responding to Patient Queries

Your staff should be prepared to answer patients' questions regarding any rapid response COVID-19 test available at the practice. Train your staff on the best way to discuss point of care testing with patients and to answer questions that might arise. The information here can be adapted for use on social media and email as well as over the phone.



Why is a dental office offering COVID-19 testing? Isn't that a medical test?



The health and safety of our patients and team is, and has always been, our top priority. All of us on staff are taking every precaution to limit the risk of COVID-19 transmission during your visit.

In response to the pandemic, we now ask every patient key questions about possible exposures to the virus, and take your temperature before bringing you to an exam room. Offering a test to see if you have the virus, even before you may be experiencing any symptoms, is another way we can help contain its spread.



Is the staff being screened with this test?



One example of steps we're taking as a team to keep everyone safe is to conduct daily health screenings of all employees. We do this by taking everyone's temperatures to make sure they don't have a fever and by asking each person a series of health-related questions every day when they report to work each day to make sure they're not experiencing any symptoms of COVID-19.

Offering you, and all of our patients, the opportunity to find out your COVID-19 status while at the practice is another way we can help keep everyone safe. The quick turn-around of test results means that patients who do test positive for COVID-19 can seek treatment faster and help them take steps to ensure the health and safety of family members, coworkers and others with whom they have been in contact.



Is the test safe? Reliable? Will it hurt? How is it done and how long does it take to get results?



The COVID-19 screening test offered in our practice is safe, easy, and reliable. Unlike the tests that had been offered earlier in the pandemic through many drive-in testing sites, which required taking a sample from way up in the nasal cavity, or from the back of your throat, all that's needed for this test is a quick (nasal swab, saliva sample). Results are available in about 15 minutes.



What's the difference between a screening and a diagnostic test?



Screening tests are typically used to detect early disease when a person appears to be healthy and asymptomatic. Diagnostic tests then confirm the presence, or absence, of a disease and are used to support treatment recommendations for patients with a specific condition.

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What happens if I test positive? Will you report me to the health department?



Anyone who tests positive for COVID-19 should notify their primary physician for guidance regarding any recommended treatments. Our practice follows the requirements of the state and local health departments. Because COVID-19 remains a significant public health risk, all health care facilities, including dental practices, are required to report COVID-19 test results to the public health department. The health department may be in touch with you in order to conduct contact tracing, which is finding out who you may have recently been in contact with so those contacts can consider getting tested for the disease.



Do I have to agree to the test?



No, our practice does not require patients to be tested for COVID-19 before treatment. We are offering this service to patients as a way to make it easier to assess their personal COVID-19 status. We will require completion of the screening questions, a temperature check, and mask usage when not in treatment as we have done before.



How much does the test cost and who pays for it? Do I pay for it out of pocket? Or is it covered under my dental benefits plan? My medical insurance? Or Medicare/Medicaid?



The test our practice offers is quite reasonable and may be covered under the federal CARES (Coronavirus Aid, Relief, and Economic Security) Act.



I'm having a medical procedure done soon. Can I use the results of this test to satisfy the hospital or out-patient facility's requirement that I have a COVID-19 test before the procedure?



Possibly. We recommend checking with the medical provider or facility to confirm whether the results of any point of care testing done in our practice will meet their requirements. Be aware that a new COVID-19 test may be required depending on the length of time between any test done in our practice and the date on which your procedure is scheduled.

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Guidance on Patient Medical Benefit Plan Claim Filing for In-Office COVID-19 Testing

A dentist who provides any services within the scope of her or his licensure may seek reimbursement from the individual or entity with financial responsibility for the patient. Although the patient has ultimate financial responsibility, the cost of necessary care may be covered in full or in part by any available benefit plan — dental or medical.

The Centers for Medicare and Medicaid Services (CMS) has announced a requirement that group health plans and individual health insurance cover administration of a COVID-19 test. Such tests include all FDA-authorized COVID-19 diagnostic tests, COVID-19 diagnostic tests that developers request authorization for on an emergency basis, and COVID-19 diagnostic tests developed in and authorized by states. COVID-19 antibody testing will also be covered. This requirement has for the moment, however, excepted dental plans from providing testing reimbursement. The full CMS announcement is available online at <https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf>.

In a dental setting the test is used as a screening tool to alert asymptomatic or presymptomatic patients of their need to seek follow up care or treatment by their physician or health care provider, and to ensure appropriate dental treatment protocols are followed. Testing also assures patients, staff, and dentists of the safety in proceeding with dental treatment. Contact your state dental association or state dental board for state specific information.

The following Questions and Answers¹ are intended to provide readers with insight and understanding of how in-office COVID-19 testing could be reported to a patient's medical benefit plan.

Questions and Answers



If I know that the patient's dental benefit plan does not cover COVID-19 testing what would be the appropriate way to suggest seeking reimbursement from the patient's medical benefit plan?



Discuss the option of seeking reimbursement from the patient's medical benefit plan and the steps involved in doing so (e.g., testing in your office vs. their primary care physician's office; the claim filing process). The patient may agree to have you deliver the test, or may thank you for the suggestion and decide to obtain the test from their primary care physician (PCP) in order to avoid any out-of-pocket expense. Remember if you are billing to a medical plan you are most likely to be treated as an out-of-network provider while the patient's PCP may be in-network allowing the patient to receive a better benefit payment.



Should I always submit a COVID-19 testing claim to the patient's dental benefit plan first, even if I know there is no coverage, before submitting a medical benefit plan claim?



It is not necessary to first submit a testing claim to the patient's dental benefit plan especially if the dental plan does not cover the service. As noted before the current coverage requirements published by CMS

¹These Q&A concern matters directly related to medical benefit claim submission. Other questions from the clinical decision-making and administrative perspectives (e.g., My patient reports having had a negative antigen test should I test for antibodies? How do I conduct the test? What test should I buy? How often should I test? Should I test my staff? Should I use an antigen vs. antibody test? etc.) are outside the scope of this guide.

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apply only to medical benefit plans. As of this writing some dental plans may be considering covering the service. Coordination between medical and dental plans may be an issue in such instances.

As of January 1, 2021 there are three CDT codes that may be used to document pathogen antibody, antigen, and molecular testing procedures delivered on or after that date. The full entries for these procedure codes, published in CDT 2021's diagnostic category of service (under Tests and Examinations) are —

D0604 antigen testing for a public health related pathogen, including coronavirus

D0605 antibody testing for a public health related pathogen, including coronavirus

D0606 molecular testing for a public health related pathogen, including coronavirus

Please note that the procedures documented and reported with these CDT codes include but are not limited to COVID-19 testing.



I do not have a participating provider agreement with my patient's medical benefit plan — does that mean I may not provide or submit a claim for services provided?



Your participating provider status with the medical benefit plan generally does not prohibit the delivery of care and submission of a claim. For reimbursement purposes you would likely be considered a non-network provider, which likely means that the patient will likely face a greater out-of-pocket expense (e.g., balance billing of any difference between your full fee for the service and the plan's reimbursement).



What fee should I charge for the service provided?



You are generally responsible for determining the appropriate fee for the service provided. Report the same full fee on a claim submitted to the patient's medical benefit plan as you would on a claim filed with the patient's dental benefit plan.



Must I submit the claim directly to the patient's medical benefit plan?



As a non-participating provider you are not required to submit the claim, but you may wish to do so as a courtesy to your patient. However, assignment of benefits may not be an option. You may seek payment from the patient at the time of service and provide the information necessary for the patient to submit the claim for reimbursement of their out of pocket expense.

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Is claim submission the same for dental benefit plans and medical benefit plans?



No, there are unique forms, formats and processes for submitting claims to medical benefit plans. They differ from submissions to dental benefit plans.



If I am not a medical benefit plan participating provider may I use the HIPAA standard electronic medical claim format, and what about paper claims?



Yes, a third-party payer must under HIPAA regulations accept an electronic claim from any provider who wishes to submit using the standard transaction format, which is known as the 837P (Professional). HIPAA regulations do not apply to any paper claim submission, whose forms are commonly referred to as the “1500 Health Insurance Claim Form” or the “CMS-1500” or simply the “1500.”



How do I access the medical claim formats?



Your practice management software is the first place to look, as some PMS have the capability to prepare both dental and medical claims. Check with your vendor for guidance, especially if you would prefer to prepare and submit an electronic medical claim — the HIPAA standard 837P — as technical programming expertise is necessary. Your current electronic transaction clearinghouse may also be able to assist, especially with establishing the same type of connections with medical third-party payers as you have with dental payers.

Should you consider preparing and submitting paper medical claims, completion instructions for the “1500” form are posted online – [NUCC \(AMA\) website](#). This website includes a sample form illustration and other information related to medical claim submission. Printed copies of the blank form are available from numerous form vendors (e.g., CMS; Quill; Office Depot).



Are there special instructions for completing a COVID-19 Point of Service test claim that is submitted to a patient’s medical benefit plan?



The American Medical Association has posted (and periodically updates) guidance on claim preparation for COVID testing for different delivery and clinical scenarios at [Special Coding Advice During COVID-19 Public Health Emergency](#). Scenario 1a therein addresses in-office sample collection and testing.

This Special Advice addresses only applicable codes for the procedure, diagnosis and place of service codes reported on the paper (“1500”) claim form or in the electronic (837P) claim format. Procedure codes include those necessary to report the In-Office Visit — the CPT equivalents of the CDT’s oral evaluation codes — in addition to the one applicable for reporting the test itself.

The AMA posts additional coding information online at: [COVID-19 Coding and Guidance](#)

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What are the key medical code sets pertaining to point of care (e.g., in-office) COVID testing that I should know about before filing a medical benefit claim?



There are a number of different code sources and values, and information about specific codes and their use is subject to ongoing update. The following table identifies and illustrates the key code sets, applicable values and placement location on the “1500” paper form as a reference only when the test is completed in the office.

Please note that claim coding and submission processes evolve. The ADA strives to post timely updates to guidance documents such as this, and also recommends checking with the various sources (NUCC, CDC, CMS and AMA) cited in this table for the most current information. Also, please refer to any federal or state statutory or regulatory (or dental plan or your practice liability insurer) for guidance on required patient record-keeping and follow-up.

CODE TYPE	SOURCE	VALUE	SHORT DESCRIPTION / ADDITIONAL INFORMATION	“1500” FIELD
Condition (Patient)	NUCC	DR	Disaster Related	10d
Diagnosis – ICD-10-CM	CDC	U07.1	Covid-19 (primary diagnosis)	21 and 24E
		Z11.59	Asymptomatic, no known exposure, results unknown or negative	
		Z03.818	Possible exposure to COVID-19, ruled out	
		Z20.828	Contact with COVID-19, Suspected exposure	
Place of Service	CMS	11	Office	24B
Procedure Code – CPT	AMA	99201-99205	In-office visit (new patient)	24D
		99212-99215	In-office visit (established patient)	
		87635	Infectious agent detection by nucleic acid (amplified probe technique)	
Procedure Code Modifier	CMS	59	Distinct procedural service	
		CR	Catastrophe/disaster related	

AMA = American Medical Association

CDC = Centers for Disease Control

CPT = Current Procedural Terminology

ICD-10-CM = International Classification of Diseases-Version 10-Clinical Modification

NUCC =National Uniform Claim Committee

COVID-19 & Lab Testing Requirements Toolkit

ADA®



How many diagnosis (ICD-10-CM) codes can be reported on a medical benefit claim?



Both the “1500” paper form and the 837P electronic claim support reporting up to 12 diagnosis codes, and there must be at least one that is referred to as the primary diagnosis. Any combination of listed codes on a paper or electronic claim format can be linked to one or more of the procedure codes reported on the claim submission using the “pointer” (“A” – “L”) associated with an individual diagnosis code.



How many procedure code modifiers can be reported for a single procedure reported on a medical benefit claim?



Up to four modifier codes can be added to each procedure listed on either a “1500” paper form or the electronic 837P format.