



## Wisconsin Pharmacy Point-of-Care Testing FAQ

Due to the rapidly changing environment with COVID-19, this document is subject to change. This document reflects information as of May 12, 2020.

Questions on point-of-care testing can be sent to [info@pswi.org](mailto:info@pswi.org).

### What authority do pharmacists in Wisconsin have to provide point-of-care tests?

Pharmacists may order and administer CLIA-waived tests. They may also order tests, including CLIA-waived tests, through a collaborative practice agreement with a physician (Wis. Stat. 450.033). This authority is independent of the COVID-19 public health emergency and therefore, does not require an executive order. The authority will continue when the public health emergency ends.

Wisconsin law is silent as to whether a pharmacist can order and administer a CLIA-waived COVID test, so our guidance defers to the federal guidance which allows for this practice.

Per the American Society of Clinical Pathology: CLIA does not expressly define who can “order or receive” a laboratory test. Rather, it reserves this authority to the states. According to a Centers for Medicaid and Medicare Services (CMS) interpretation of CLIA, if a state does not prohibit a patient from ordering or receiving laboratory tests, CLIA would not bar an individual from obtaining testing. Thus, in such states DAT would be legal. Clinical laboratories are not required to allow DAT, however, laboratories would need to establish policy as to whether it would provide DAT and which tests, if any, it would provide.

### What CLIA-waived tests are available?

Pharmacists can offer [CLIA-waived tests designated by the CDC](#). This includes tests for Influenza, Streptococcus Group A, Hepatitis C, and COVID-19. The list of CMS CLIA-waived tests is [here](#). As of May 12, 2020, there are no approved serology tests. If tests become approved, they will be included in the list of CLIA-waived tests.

The American Pharmacists Association designed a [COVID-19: Demystifying Testing for the SARS-CoV-2 Virus document](#) explaining more about COVID-19 testing. On May 4, 2020, CMS released a [memorandum](#) with guidance on the types of COVID-19 tests and CLIA certificates required for each.

The State of Wisconsin has developed a [website](#) where healthcare professionals can request testing supplies at no charge. Supplies may be limited and are available at no cost if approved.



### **What is a CLIA-waiver?**

Per the CDC, "All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Although CLIA requires that waived tests must be simple and have a low risk for erroneous results, this does not mean that waived tests are completely error-proof. Errors can occur anywhere in the testing process, particularly when the manufacturer's instructions are not followed and when testing personnel are not familiar with all aspects of the test system. Some waived tests have potential for serious health impacts if performed incorrectly. For example, results from waived tests can be used to adjust medication dosages, such as prothrombin time testing in patients undergoing anticoagulant therapy and glucose monitoring in diabetics. In addition, erroneous results from diagnostic tests, such as those for human immunodeficiency virus (HIV) antibody, can have unintended consequences. To decrease the risk of erroneous results, the test needs to be performed correctly, by trained personnel and in an environment where good laboratory practices are followed." For more general information about POCT, please visit the [CDC Ready, Set, Test Training](#) where you can complete a general CLIA-waiver training course.

### **How Do I File a CLIA Waiver?**

The application process for a certificate to provide a CLIA-waived test takes less than 30 minutes to complete, but waiting for the certificate may take 6-8 weeks. When a pharmacy completes the CLIA waiver application, they need to specify the exact test name and company used for testing. NCPA provided a [15-minute video](#) that succinctly describes the process of filling out [the CMS form](#). Additionally, [a step-wise document from NCPA/CPESN](#) provides details about the CLIA waiver process.

### **What If I Want to Add Additional Tests to My Current Waiver?**

When a pharmacy desires to add tests to their current CLIA waiver, pharmacies can send an email to [DHSDQACLIA@wi.gov](mailto:DHSDQACLIA@wi.gov) with the name of the laboratory (pharmacy), CLIA number, and name of the test and test system that will be used.

Related to COVID-19, CMS has also issued a [CLIA Frequently Asked Questions \(FAQs\)](#) document for further guidance during the COVID-19 emergency.

### **Who is ordering the test?**

Under a collaborative practice agreement, the authorizing physician is the provider ordering the test. For CLIA-waived tests ordered by a pharmacist, the pharmacist is the provider ordering the test. Tests ordered by non-physicians may not be covered by payors.

### **What personal protective equipment (PPE) is needed and how do I properly wear?**

Related to COVID-19, health care personnel should adhere to Standard and Transmission-based Precautions when caring for patients with SARS-CoV-2 infection. Recommended PPE is described in the Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Health Care Settings ([here](#)). The CDC created a video demonstrating how to don PPE found [here](#).



### **Where do I report tests?**

The [Wisconsin Electronic Disease Surveillance System \(WEDSS\)](#) is a secure, web-based system designed to facilitate reporting, investigation, and surveillance of communicable diseases in Wisconsin. Per Wis. Stats. § 252.05, any health care provider (including pharmacists) who knows or has reason to believe a person treated or visited by him or her has a communicable disease is required to report to WEDSS. Per Wis. Admin. Code § DHS 145.04(1), this includes reporting of a case or suspected case. Information is entered in WEDSS upon testing, not upon results. Therefore, pharmacies will enter testing information into WEDSS, whether the test is processed onsite or in an offsite lab. The county health department contacted will be the patient's county of residence.

**CATEGORY I:** Report immediately (within 24 hours) by phone to local health officer *and* in WEDSS upon identification of a case or suspected case. Category I tests includes COVID-19.

**CATEGORY II:** Report within 72 hours to WEDSS upon recognition of a case or suspected case. Category II includes Influenza A virus infection / novel subtypes, Hepatitis C (more info in Wis. Stat 252.12), Lyme disease, and Streptococcus disease (all invasive disease caused by Groups A and B Streptococci).

**CATEGORY III:** Only includes HIV (more info in Wis. Stat. 252.12 - 252.15). Not reported in WEDSS and has separate set of instructions.

Watch a video [overview of WEDSS](#) (recorded module, approx. 5 minutes). Presentation will only open in Internet Explorer or Safari web browsers.

Contact your local health department or the [Division of Public Health \(DPH\) WEDSS staff](#).

WEDSS documents are located on the WEDSS Sharepoint site. You must have a Wisconsin Logon Management System (WILMS) account in order to use WEDSS or access these documents. If you do not have a WILMS account, please send an email to [DPH WEDSS staff](#) to request instructions.

Per Wis. Stat. 252.02, if a violation of this section is reported to a district attorney by a local health officer or by the department, the district attorney shall forthwith prosecute the proper action, and upon request of the department, the attorney general shall assist.

Per Wis. Stat. 252.25, any person who willfully violates or obstructs the execution of any state statute or rule, county, city or village ordinance or departmental order under this chapter and relating to the public health, for which no other penalty is prescribed, shall be imprisoned for not more than 30 days or fined not more than \$500 or both.



### **Will a patient's insurance cover the test? How will the pharmacy be reimbursed?**

Pharmacists may order and administer CLIA-waived tests without a CPA. Per the Wisconsin Insurance Commissioner, the new law that requires COVID-19 testing be covered requires insurers to cover the same as an insurer covers testing for any infectious disease without imposing any cost sharing. If the insurance contract currently has a specific exclusion for testing by pharmacists, then they would be able to apply that exclusion. If the contract is silent and does not contain specific exclusions, then they could not exclude pharmacists. Therefore, if payors are not paying pharmacists for the tests, a CPA would be needed in order to bill under the physician's NPI as the delegator of the service.

In regards to Medicaid, billing information can be found [here](#). It is recommended a CPA be used to complete billing through Medicaid.

In regards to Medicare, a written order from a physician or other healthcare practitioner is not required to get tested for COVID-19 as of April 30, 2020. If you are not enrolled in Medicare Part B, this [video](#) explains the fast and free method of enrolling, which is necessary to bill Medicare for COVID-19 tests.

On May 4, 2020, CMS released a [memorandum](#) stating, "Medicare will pay for COVID-19 tests performed by pharmacists as part of a Medicare enrolled laboratory. A pharmacist also may furnish basic clinical services, such as collect lab samples, under contract with a doctor or practitioner, in accordance with a pharmacist's scope of practice and state law. Beneficiaries can get tested at "parking lot" test sites operated by pharmacies consistent with state requirements."

Additionally, the United States Department of Health and Human Services has launched the [COVID-19 Uninsured Program Portal](#), which allows health care providers who have conducted COVID-19 testing to uninsured COVID-19 individuals to request claims reimbursement. Additional information on eligibility and the process are available on the [HRSA portal page](#).

### **What advice must I give to patients will they wait for their test results, or after the results are received?**

Per Wisconsin Department of Health Services, providers should inform patients to self-isolate (read more [here](#)). Patients should also be advised that the public health department will be contacting them after each COVID-19 test and may contact them after other positive point-of-care tests listed as Category I, II, III diseases (examples: Influenza, Streptococcus Group A, Hepatitis C).

Per Wis. Stat. 252.19, no person who is knowingly infected with a communicable disease may willfully violate the recommendations of the local health officer or subject others to danger of contracting the disease. No person may knowingly and willfully take, aid in taking, advise or cause to be taken, a person who is infected or is suspected of being infected with a communicable disease into any public place or conveyance where the infected person would expose any other person to danger of contracting the disease.



### **What liability considerations should I be aware of?**

Check with your insurance providers and legal advisors prior to offering and administering point-of-care tests.

Wis. Stat. 895.4801 provides immunity for health care providers, including pharmacists, during the COVID-19 public health emergency. During the COVID-19 public health emergency, any health care professional, health care provider, or employee, agent, or contractor of a health care professional or health care provider is immune from civil liability for the death of or injury to any individual or any damages caused by actions or omissions that satisfy all of the following:

The action or omission is committed while the professional, provider, employee, agent, or contractor is providing services during the state of emergency declared under s. 323.10 on March 12, 2020, by executive order 72, or the 60 days following the date that the state of emergency terminates.

The actions or omissions relate to health services provided or not provided in good faith or are substantially consistent with any of the following:

1. Any direction, guidance, recommendation, or other statement made by a federal, state, or local official to address or in response to the emergency or disaster declared).
2. Any guidance published by the department of health services, the federal department of health and human services, or any divisions or agencies of the federal department of health and human services relied upon in good faith.

The actions or omissions do not involve reckless or wanton conduct or intentional misconduct.