

COVID-19 COVID-19 Testing Sites

January 14, 2022

Frequently Asked Questions

Q: Does the Illinois Department of Public Health regulate COVID-19 testing sites?

A: Illinois law does not assign the Illinois Department of Public Health (Department) or any state agency authority to license or authorize the operations of private specimen collection and testing sites for COVID-19, with a limited exception. The Department regulates laboratories that perform testing for the purpose of diagnosis and treatment pursuant to federal Clinical Lab Improvement Amendments (CLIA) and state rules. Point-of-care test sites (POC sites) are sites where there is a rapid test performed on site. POC sites are required to operate under a CLIA certificate. For testing sites operating under a CLIA-certified laboratory, the Department can investigate complaints that are potential violations of the CLIA regulations at the POC sites, which are considered extensions of the CLIA-certified laboratory. Ultimately, the CLIA-certified laboratory is responsible for CLIA violations at the POC site.

Q: What do CLIA regulations cover?

A: CLIA regulations establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid and tissue, for the purpose of diagnosis, prevention, treatment of disease or overall assessment of health. Most CLIA violations discovered at POC testing sites relate to improper specimen type, environmental conditions, collection/specimen integrity, erroneous results and failure to follow instructions for test use.

CLIA regulations do not set forth personal protective equipment (PPE) requirements, specific turnaround times for test results, crowd capacity or a cap on the kinds of fees/charges for testing.

CLIA regulations can be found at https://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/downloads/som107ap c lab.pdf.

Q: How do I know if the lab that is processing my test is CLIA-certified?

A: Upon arrival at the testing site, ask which laboratory your specimen will be sent to, and ask for lab's CLIA number. To find out if a lab is certified visit:

https://qcor.cms.gov/advanced_find_provider.jsp?which=4&backReport=active_CLIA.jsp. This website will show the "certificate type" for the lab, and whether the lab is functioning under a CLIA certificate.

Q: Can I file a complaint with the Department against a CLIA-certified lab?

A: You may file a complaint with the Department by visiting the following site: https://dph.illinois.gov/content/dam/soi/en/web/idph/files/forms/clia-ccr-complaint-form-fields-041216.pdf

Q: Who is authorized to perform COVID-19 tests?

A: The public is advised that COVID-19 tests are being administered by licensed healthcare professionals and by unlicensed persons. Persons administering COVID-19 tests are not required under Illinois law to be licensed healthcare professionals.



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Q: Is it permissible for the testing site to ask me for payment for the test at the time of service?

A: The testing site should not ask you for payment at the time of the test. If you have insurance, the testing site may ask for that information and bill your insurance. The Families First Coronavirus Response Act generally prohibits private health insurance coverage or group health plans from imposing cost-sharing on both the test itself and the health care provider's administration of the test, as long as the purpose of the testing is for your individualized diagnosis or treatment of COVID-19. Additionally, health care providers who have received federal funds from the Provider Relief Fund are contractually prohibited from balance billing you for the test or its administration, even if they are out-of-network for your insurance plan. However, health insurance plans are not generally required to provide coverage of COVID-19 testing for publicsurveillance or employment purposes. Short-term, limited duration insurance policies and "excepted benefits" policies may subject members to some portion of the provider's fee.

If you do not have insurance, regardless of citizenship or immigration status, the provider may bill the <u>Illinois HFS COVID Portal</u> or the federal <u>HRSA COVID-19 Uninsured Program</u>. Providers who participate in, and are reimbursed from these programs, for qualified COVID-19 related services rendered to you, are not allowed to collect any additional fees.

Regardless of your insurance status, if you experience or witness any potential violations of this requirement you can report the matter to the Office of the Inspector General, U.S. Department of Healthand Human Services, by calling 1-800-HHS-TIPS or the website <u>TIPS.HHS.GOV</u>. If you are a Medicaid customer or are uninsured and you have been asked to pay out of pocket for a COVID-19 test, please call HFS at 877-805-5312 and press 9 for assistance.

Q: Is the testing site allowed to ask for my personal information or protected health information before it conducts a COVID-19 test?

A: Yes, the testing site is allowed to request personal contact information and information related to health-related matters that are used as screening tools before administering the COVID-19 test. However, testing sites, like any health care provider, must follow privacy regulations under federal and state law, including the Health Insurance Portability and Accountability Act (HIPAA). If you believe the testing site has violated HIPAA, you may file a complaint with the Department of Health and Human Services (DHHS) at https://www.hhs.gov/hipaa/filing-a-complaint/index.html.

Q: What is the best way to find a reliable COVID-19 testing site?

A: Testing is available at 10 free State community-based testing sites, which are listed on the Department's website at https://dph.illinois.gov/covid19/testing.html. The website also provides a link to free SHIELD Illinois testing locations. You can also reach out to your primary health care provider, the nearest urgent care center, local pharmacy, and your local health department to ask about testing options.



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Q: Where can I file a complaint if I have concerns about a testing site?

- A: Individuals are encouraged to file a complaint on the <u>Attorney General's website</u> if they believe they have been the victim of fraud, if they were not charged at the time of a COVID-19 test but later receive a bill for testing services, or if they have experienced or witnessed price gouging. On January 11, 2022, the Attorney General's Office issued this <u>consumer alert</u> relating to pop-up COVID testing sites.
 - You may contact the municipality in which the business is located and file a complaint. Most municipalities require business permits or licenses to operate within their jurisdiction.
 - You may also contact the Better Business Bureau (BBB) and file a complaint at https://www.bbb.org/file-a-complaint.

Q: What if I never receive my test result or am a close contact of a confirmed or probable case and am unable to find a test?

A: Regardless of symptoms, you should follow the Centers for Disease Control (CDC) guidance on isolation, quarantine, and masking which can be found at https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html.







Questions about COVID-19?

Call 1-800-889-3931 or email dph.sick@illinois.gov

Illinois Department of Public Health - www.dph.illinois.gov