

HOW TO GET CERTIFICATION FOR WORKPLACE COVID-19 TESTING



IS A CLIA CERTIFICATE NEEDED TO PERFORM AN OTC TEST INTENDED FOR HOME USE?

Generally, a test that has been authorized or cleared specifically for over the counter home use by the FDA is not regulated under CLIA when that test is *self-administered*, that is, the individual tests themselves and interprets the results themselves according to the instructions for use.

But if the test is either performed by someone other than the individual being tested (e.g., other staff, employee health personnel), or the results are interpreted and reported by someone other than the individual, then a CLIA certificate would be required.



HOW DOES AN EMPLOYER APPLY FOR A CLIA CERTIFICATE?

An employer can follow the [quick start guide](#) and complete the [CMS-116 Application](#) to get a CLIA certification. Completed forms should be sent to the [state agency](#) for the employer's state. An employer can apply for a single CLIA certificate for multiple locations. Multiple locations can be listed as separate temporary testing sites under one CLIA certificate. The person listed as "laboratory director" on the CLIA certificate is responsible for all testing administered at each location under the certificate. For a Certificate of Waiver, CMS does not require that the "laboratory director" be a physician or medical professional; however, you will need to check with the [state agency](#) where the employer is located to see if there are any state requirements for "laboratory directors." There is no limit on the number of temporary testing sites that can be listed under one certificate.



WHAT IS CLIA? WHY WOULD AN EMPLOYER NEED A CLIA CERTIFICATE?

The [Clinical Laboratory Improvement Amendments \(CLIA\)](#) of 1988 are federal regulatory standards that ensure patient laboratory test results are accurate, reliable, and timely. CLIA applies to testing performed on humans, including testing performed in the workplace.

An employer needs a certificate to perform on-site COVID-19 testing. This certificate shows that an employer meets CLIA quality and safety requirements to follow test manufacturers' instructions and provides accurate results.



HOW QUICKLY CAN AN EMPLOYER START TESTING?

Once any applicable state requirements are met, testing can begin as soon as the Certificate of Waiver application is submitted to CLIA.

Requirements can vary by state, so check with your [state agency](#) before you begin testing if you don't have a CLIA certificate yet.



WHICH CLIA CERTIFICATE DOES AN EMPLOYER NEED?

On-site COVID-19 tests generally require employers to [get a Certificate of Waiver](#). These tests are generally of low complexity and therefore most employers would only need a Certificate of Waiver.

A Certificate of Waiver costs \$180. If an employer continues to perform testing and pays the certificate fee, the certificate will be automatically renewed every 2 years. CMS recommends keeping a copy of the CLIA certificate on file at each on-site testing location.



DOES THE GOVERNMENT INSPECT EMPLOYERS FOR CLIA COMPLIANCE?

A facility that holds a CLIA Certificate of Waiver is not usually inspected, but it can be if a complaint is received. CLIA inspectors can make in-person visits to testing locations to make sure they meet CLIA requirements. Please refer to the [How To Obtain A Certificate of Waiver](#) brochure for additional information.

EMPLOYER TESTING SCENARIOS FOR OVER THE COUNTER (OTC) HOME TESTS AND CLIA APPLICABILITY

SCENARIO	CLIA CERTIFICATE NEEDED
An employer has someone employed by their organization (e.g., other staff, employee health personnel) who will perform COVID-19 testing on its employees.	YES
An employer is using an FDA authorized test kit that is NOT an over the counter (OTC) test intended for home use.	YES
An OTC test intended for home use is performed by someone other than the employee being tested (e.g., other staff, employee health personnel).	YES
An OTC test intended for home use is performed and the result is interpreted by someone other than the employee being tested (e.g., other staff, employee health personnel).	YES
An employer has someone employed by their organization who only collects employee COVID samples for testing. The samples are then sent for COVID testing in a CLIA certified facility.	NO
An employee performs and interprets their own COVID-19 testing using an OTC test intended for home use and then gives/provides/shows the result to the employer.	NO
An employer or other entity provides OTC test kits intended for home use to employees so that they can test and interpret the results themselves.	NO
An outside facility is contracted by the employer to perform specimen collection and the samples are sent to a CLIA certified facility.	NO
An employer has contracted an outside CLIA certified facility to perform COVID-19 testing on its employees.	NO