

Over-The-Counter (OTC) Home Testing and CLIA Applicability
Frequently Asked Questions November 22, 2021, Updated March 4, 2022

1. Does use of over the counter (OTC) tests authorized by the FDA intended for home use require CLIA certification?

Response: Generally, a test that has been cleared, approved, or authorized specifically for home use by the FDA is not regulated under CLIA when that test is self-administered in accordance with the FDA's authorization and authorized labeling.

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. (See Note)

Certain tests may be cleared, approved, or authorized by the FDA for home use. Some of these may require a prescription and be referred to as "prescription home use tests," while others do not require a prescription, and are referred to as "over the counter (OTC) home tests."

Note that testing performed by a parent or guardian for a child or adult unable to test themselves, **when authorized in the manufacturer's Instructions for Use (IFU)**, is considered self-testing, so would generally not fall under CLIA oversight.

Generally, there are separate Instructions for Use designated for OTC home use (i.e., self-testing) and for healthcare provider facilitated testing, which would generally need to be performed in a facility operating under a CLIA certificate. As such, the appropriate instructions must be followed depending on the setting in which the test is used.

Updated Response (3/4/2022):

Generally, a test that has been cleared, approved, or authorized specifically for home use by the FDA is not regulated under CLIA when that test is self-administered in accordance with the FDA's authorization and authorized labeling. 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 or reported by someone other than the individual, then a CLIA certificate would be required.

Certain tests may be cleared, approved, or authorized by the FDA for home use. Some of these may require a prescription and be referred to as "prescription home use tests," while others do not require a prescription, and are referred to as "over the counter (OTC) home tests." Note that such testing when performed by an individual, including a parent or guardian, for a child or an adult who is unable to test themselves (e.g., an individual assisting a child or adult who is unable to test themselves due to a physical disability in a home or congregate setting), to the extent authorized in the manufacturer's Instructions for Use (IFU), is considered self-testing for purposes of CLIA and would not require a CLIA certificate.

Generally, there are separate Instructions for Use designated for OTC home use (i.e., self-testing) and for healthcare provider-facilitated testing, which would generally need to be performed in a facility operating under a CLIA certificate. As such, the appropriate instructions must be followed depending on the setting in which the test is used.

For additional questions related to these EUAs and their use, please contact the FDA at COVID19DX@fda.hhs.gov.

2. Do facilities such as schools, shelters, jails, etc., need a CLIA certificate to perform OTC tests authorized by the FDA for home use?

Response: Yes, a facility where a staff member is performing testing and/or interpreting / reporting test results needs a CLIA certificate to perform testing, even if the test is authorized by the FDA for home use. This includes testing using OTC home tests performed by someone other than the individual in a facility such as a school, shelter, jail, or other location.

The purpose of the CLIA requirements is to ensure that the test results that patients or their health care providers receive from a facility are accurate and reliable. Laboratories or facilities that wish to become CLIA certified must apply for a CLIA Certificate. (See Note)

3. What is the rationale for the distinction between an OTC home test being self-administered and being administered by someone in a facility outside of the home?

Response: CLIA prohibits any person from soliciting or accepting human specimens without a valid CLIA certificate if the test results are used to diagnose, prevent, treat, or assess health. This includes testing using OTC home tests performed by someone other than the individual being tested in a facility such as a school, shelter, jail, or other location. The purpose of the CLIA requirements is to ensure that the test results that patients or their health care providers receive from a facility are accurate and reliable. Facilities that wish to become CLIA certified laboratories must apply for a CLIA Certificate. (See Note)

Some states have laboratory requirements that are more stringent than CLIA so laboratories in those states must meet the more stringent requirements. Please contact the appropriate State Agency (SA) to inquire about state requirements. Helpful link: [State Agency Contacts](#)

4. Can over the counter (OTC) home tests be used in facilities that perform waived, moderate and high complexity testing?

Response: Yes. Over the counter (OTC) home tests may also be used in CLIA-certified facilities that perform waived, moderate and high complexity testing; provided the tests have been authorized for use in those settings by the FDA.

Tests issued Emergency Use Authorization (EUA) are not categorized, so they will not be found in the FDA's [CLIA Database](#). However, the settings in which an EUA-authorized test may be used are described in the Letter of Authorization issued by the FDA. Tests authorized under EUA for use at the point of care (POC) are deemed to be CLIA waived tests while the EUA is in effect. The FDA's [Tables of In Vitro Diagnostics EUAs](#) provides regularly updated lists of tests granted EUA, including information about the authorized setting(s).

The "Authorized Setting(s)" column describes the setting in which a test is authorized to be performed, i.e., at home, or in a waived, moderate complexity or high complexity setting. If an EUA has been authorized for OTC home use, "OTC" will be reflected in the "Attributes" column, and "Home" will be reflected in the "Settings" column. For example, to determine if an EUA is

authorized to be performed in a waived setting, please ensure that a “W” is reflected in the “Authorized Setting(s)” column.

5. Can over the counter (OTC) home use testing be performed in a setting other than homes (e.g. workplace)?

Response: Yes. Please see the [Tables of In Vitro Diagnostics EUAs](#) for a list of tests granted an EUA. The site is updated as more tests receive EUA. While tests with EUA are not categorized according to test complexity, they are authorized by the FDA for specific settings. The “Authorized Setting(s)” column describes the setting in which a test is authorized to be performed, i.e., a waived, moderate complexity or high complexity setting, or home.

In the case of self-testing being performed in a setting other than home (e.g. workplace), if the individual performs and interprets their own test and then shows their test result to someone else (e.g., employer) as proof of their result, we do not consider this to be interpretation or reporting, since the individual has performed and interpreted their own test in accordance with the instructions for use of that particular test. In this case, CLIA certification is not required.

6. Can a COVID-19 test be used for self-testing at my facility if that test has not been authorized by the FDA for OTC home use without a CLIA certificate?

Response: No. A COVID-19 test may only be used in the settings authorized by the FDA. Any test not authorized for home use is only authorized for use in settings operating under a CLIA certificate. (See Note)

7. Can a staff member or employee of a facility provide assistance to an individual performing self-testing?

Response: Yes. Individuals who self-administer a test (in their own home or another location) with a test that has been cleared, approved, or authorized by FDA specifically for home use are not regulated under CLIA. An employee of a facility (i.e., home health agency, hospice, etc.) that provides assistance to an individual while that individual self-administers a home use test is not, by virtue of that assistance, subject to CLIA as long as the test is performed by the individual in accordance with the instructions for use of that particular test. However, if an employee performs the test or interprets the test result for the individual, the facility is subject to CLIA requirements. (See Note and Question 1)

8. If an OTC test is used in a CLIA certified facility, does that make the COVID-19 result reportable?

Response:

Yes, unless the test is performed as a self-test where an individual self-administers the test in accordance with the FDA authorization.

All CLIA-certified laboratories that perform or analyze any test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report all SARS-CoV-2 test results, regardless of the type of laboratory (type of CLIA

certificate) performing the testing. All negative and positive SARS-CoV-2 results must be reported irrespective of the method (e.g., molecular, lateral flow) used.

Compliance with The Secretary's [January 8, 2021 Guidance](#) and CDC guidance [regarding reporting of SARS-CoV-2 test results](#) does not fall under CLIA oversight. CLIA only assesses if a laboratory has reported, or attempted to report, the test results. In order to be in compliance with the CLIA reporting requirements, a laboratory will need to have documentation that it reported SARS-CoV-2 results or at least attempted to report the results. CLIA is not prescriptive as to the type of documentation.

For questions related to the specific details in HHS' [January 8, 2021 Guidance](#), to include any questions with regards to how or where to report or for any specific guidance questions on reporting can go to CDC's EOC mailbox, eocevent405@cdc.gov.

You may find these additional links helpful:

- HHS Laboratory Data Reporting for COVID-19 Testing: [HHS Laboratory Data Reporting COVID-19 FAQs](#)
- CDC Reporting COVID-19 Laboratory Data: [How to Report COVID-19 Laboratory Data](#)

NOTE: A CLIA certificate is required if the test results are used to diagnose, prevent, treat, or assess health. The purpose of the CLIA requirements is to ensure that the test results that patients or their health care providers receive from a clinical laboratory are accurate and reliable. Tests are generally categorized as high complexity, moderate complexity, or waived. Generally, high complexity tests may be performed by laboratories certified under CLIA that meet requirements to perform high complexity tests, moderate complexity tests may be performed by laboratories certified under CLIA that meet requirements to perform moderate complexity tests, and waived tests may be performed by facilities operating under a CLIA Certificate of Waiver.

Different types of CLIA certificates are available depending on the type of testing your laboratory performs. OTC home tests may be performed in CLIA certified laboratories holding any CLIA certificate, including laboratories certified under CLIA that meet requirements to perform high complexity tests or moderate complexity tests and facilities operating under a CLIA Certificate of Waiver. However, if the test kit is used "off-label" (i.e., not used as per the IFU, or if the IFU are modified), the test complexity defaults to high complexity and facilities must be able to meet CLIA requirements for high complexity testing.

Helpful Links

- [CLIA Database](#) - The test categorization and the settings in which a test is cleared, approved, or authorized for use is determined by the FDA. The FDA categorizes tests under CLIA and maintains a [CLIA Database](#) that lists all laboratory tests that have been categorized under CLIA. Any test that has not been categorized is considered high complexity by default. FDA's [CLIA Database](#) can be used to confirm the categorization of a particular test.
- [Tables of In Vitro Diagnostics EUAs](#)
- FDA Contact Information for general COVID questions: COVID19DX@fda.hhs.gov

- CDC Contact Information for questions related to the specific details in HHS' January 8, 2021 Guidance, to include any questions with regards to how or where to report or for any specific guidance questions on reporting: eocevent405@cdc.gov