



CLIA Waived Testing at Camp

January 2021

With the introduction of COVID in 2020, we are learning that more camps are considering testing as part of their risk mitigation strategy for 2021. This is an important consideration and one that might be a welcome addition to the other nonpharmacologic interventions (NPIs) already being used at camps. The NPIs include screening, cohorting, handwashing, sanitizing, ventilation, face masks, and physical distancing. Each of these activities, when used in conjunction with the others, helps to reduce the risk of communicable disease at camp.

COVID-19 testing may be something your camp is considering. If so, your camp should have a CLIA certificate of waiver (COW). Many special needs camps are already familiar with this requirement and have a CLIA waiver in place as they historically have had the staffing and capability to do waived testing. Please review the information below if you are considering testing as part of your NPI strategy for 2021. We hope this document provides you guidance regarding steps to comply with CDC and FDA requirements for waived testing at camp.

What is a CLIA waiver?

A Clinical Laboratory Improvement Amendment (CLIA) Certificate of **Waiver** is a **certification** that allows a facility, primarily laboratories, to legally examine a person through **waived** tests in order to assess health, diagnose, and determine treatment.

Who needs a CLIA waiver?

CLIA generally **requires** all facilities that perform even one applicable test, including **waived** tests, 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, or the assessment of the health of, human beings” to obtain a CLIA certificate and meet CLIA regulatory requirements.

What tests are CLIA waived?

Waived tests include **tests** 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. **Waived testing** is designated by CLIA as simple **tests** that carry a low risk for an incorrect result. Historically, waived tests have included many point-of-care tests such as influenza tests, strep tests, and other simple tests.

FDA Clarifies CLIA-waived Status for Point-of-Care SARS-CoV-2 Tests under Emergency Use Authorizations

The U.S. Food and Drug Administration (FDA) recently clarified that, when it grants an Emergency Use Authorization (EUA) for a point-of-care test, that test is deemed to be CLIA-waived. For the duration of the national emergency declaration for COVID-19, such tests can be performed in any patient care setting that operates under a [CLIA Certificate of Waiver or Certificate of Compliance/Certificate of Accreditation](#).

How much does a CLIA waiver cost?

The **fee** for a Certificate of **waiver** is \$150.

CLIA Certificate of Waiver (COW) Requirements:

To qualify for a certificate of **waiver**, your camp must only perform **tests** that have received the **CLIA waived** status. If you meet this requirement, simply fill out the application form CMS-116 at the CMS website (attached below). The COW is valid for two years.

Form CMS 116: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>

How to Obtain a CLIA Certificate of Waiver

https://www.cdc.gov/labquality/waived-tests.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fclia%2Fwaived-tests.html

CLIA Waiver – Additional Resources and Readings

1. <https://www.cdc.gov/clia/test-complexities.html>
2. <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>
3. <https://www.cdc.gov/labquality/waived-tests.html>
4. <https://www.acponline.org/practice-resources/business-resources/laboratory-proficiency-testing-program/clia-waived-testing>
5. https://www.whitehatcom.com/POCWebMtgs/Slides/K_Dyer_D_Hassan_CLIA_Waived_Testing_061714.pdf