

Q/A: Clinical Laboratory Improvement Amendments (CLIA) Requirements for Court Programs

This document is intended to provide guidance for court programs that include drug testing. This guidance applies to ANY program, including pre-trial, diversion, and treatment court programs that utilize drug testing. Programs can contact WI Department of Health Services (DHS) at DHSDQACLIA@dhs.wisconsin.gov for additional information. Links to additional resources can also be found at the bottom of this document.

Q: If a site is doing testing just to determine compliance with a court order (such as bail monitoring), do they need a CLIA waiver?

A: Yes, a CLIA waiver is required.

Q: If a site uses instant read CLIA waived tests, but sends positive test results to a CLIA certified lab for further analysis, does the collection site need to obtain a CLIA waiver?

A: If testing of any kind is being performed, then a CLIA waiver would be needed. This includes waived testing which would be done as a preliminary reading before the sample is sent out for further analysis or confirmatory result.

Q: If a site is just a collection site (the fluid is collected, but no analysis or instance read test is utilized) and the sample is sent to a CLIA certified lab for further analysis, does the collection site need to obtain a CLIA waiver?

A: Sample collection only would not be considered CLIA, and a CLIA certificate would not be needed.

Q: If the site does need to obtain a CLIA waiver, what is the process for doing that?

A: The Center for Medicare and Medicaid (CMS) [Laboratory Quick Start Guide](#) explains how to apply for a CLIA waiver. The [application](#) can be found on the first page of the guide.

Resources

Wisconsin Department of Health Services CLIA Information Sheet for Treatment Courts and Programs: <https://www.dhs.wisconsin.gov/publications/p01176.pdf>

Wisconsin Department of Health Services CLIA Resources: <https://www.dhs.wisconsin.gov/regulations/labs/publications.htm>

Centers for Disease Control (CDC) Waived Tests: <https://www.cdc.gov/labquality/waived-tests.html>