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## Memorandum for Schools Conducting On-Site Clinical Testing

This memorandum is to provide an update on the process and requirements for schools and districts conducting certain on-site clinical testing during the 2022-2023 school year. The Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulations require that any district or school administering CLIA-waived tests, including but not limited to certain glucose, ketone, and COVID-19 tests, must apply for a CLIA Certificate of Waiver.

Districts and schools that were participating in the statewide COVID-19 testing program and did not have their own CLIA Certificate of Waiver had been doing so under a statewide Certificate of Waiver. For the 2022-2023 school year, districts and schools that are administering CLIA-waived tests have been applying for their own CLIA Certificate of Waiver to do so. For districts and schools that would like to conduct COVID-19, glucose and ketone CLIA-waived testing, DPH has obtained a statewide waiver through the 2022-2023 school year. In order to be added to this waiver, schools and districts must complete this online form. Districts and schools that have already obtained or applied for their own CLIA waiver do not need to fill out the form or be added to the statewide waiver.

All districts or schools administering or planning to administer CLIA-waived tests in and beyond fall 2023 must still apply for their own CLIA waiver by March 31, 2023 to ensure transition to their own waiver for the 2023-2024 school year. Applications should be submitted through the <a href="Department of Public Health (DPH) Clinical Laboratory Program">Department of Public Health (DPH) Clinical Laboratory Program</a> by e-mailing the completed <a href="CMS-116 CLIA application">CMS-116 CLIA application</a> to <a href="CLIALab@mass.gov">CLIALab@mass.gov</a>.

## For more information:

- Frequently Asked Questions General Testing Questions for Schools, Districts and School Nurses, June 9, 2022, updated October 3, 2022
   <a href="https://www.doe.mass.edu/covid19/testing/faq.docx">https://www.doe.mass.edu/covid19/testing/faq.docx</a>
- CLIA Application CMS-116 CLIA application
- CMS CLIA Application Quick Start Guide
- CMS CLIA FAQ