ARIZONA DEPARTMENT
OF HEALTH SERVICES

CLIA Information for Point-of-Care Testing

SARS-CoV-2 (or COVID-19) assays/tests are authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that perform high, moderate, or waived complexity tests. Some of these tests (such as the antigen assays) are also authorized for use at the Point-of-Care (POC), i.e. in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. If you are unsure of your CLIA status, please contact the State CLIA Licensing program at cliawaivers@azdhs.gov.

NOTE: Tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

If you need to apply for a CLIA Certificate of Waiver, complete the CMS-116 form and visit the ADHS Clinical Laboratory Certification webpage for more information. Email completed applications (preferred) to cliawaivers@azdhs.gov or fax to 602.364.0759.

General information regarding How to Obtain a CLIA Certificate of Waiver is available at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf.

- Each location needs to have a CLIA certificate unless one of the following applies:
  - Facilities performing limited public health testing may share a single CLIA Certificate of Waiver (multiple site exception) if they are a not-for-profit, Federal, State, or local government.
    - Example: School District ABC has or applies for a CLIA Certificate of Waiver. The district operates as a single system and can have one CLIA certificate shared among the schools.
    - This means that there is only **one** CLIA certificate (one CLIA number, one director, one tax ID) and that the director is responsible for ensuring that testing is performed per manufacturer's instructions and the current manufacturer's instructions are retained for each site under that CLIA number. Each site would be required to follow the FDA Emergency Use Authorization (EUA) instructions for each FDA EUA approved COVID-19 test performed.
    - Each site would need to retain a copy of the CLIA certificate that indicates the main site as well as a copy of the multiple site screen prints provided by the CLIA office.
  - Facilities performing as a mobile unit may be covered under a certificate of a designated primary site using its address.
    - Mobile unit is defined as a self-contained movable laboratory where all testing is performed on the mobile unit.

- Completing the CMS-116 form
  - The first 5 pages of the form are the application (the last few pages are instructions).
  - This is a fillable form and can be completed electronically.
  - Follow the form instructions. The following are provided to highlight a few sections.
    - Section III: Type of Laboratory (e.g., Home Health Agency, School/Student Health)
    - Section V – ONLY if multiple sites and indicate how many
      - Copy this page (page 2) if more than 2 additional sites and attach
    - Section VI Waived Testing
      - List COVID19 assay and estimated annual number samples