

CLIA Updates for Antigen Testing

- Each site performing rapid antigen point-of-care test must have a CLIA waived/PPM certificate.
- Districts must **update** their CLIA certificate to **include** rapid antigen point-of-care testing.
- Districts with an existing CLIA Certificate must **email their CLIA # and COVID-19 test method** to CLIALAB@vdh.virginia.gov, so it can be added to the test menu in the CLIA system.

Multi-Site Exception

Steps for Updating on the CMS116 (CLIA Application for Certification)

For locations that want to conduct temporary testing at another location, the **Multi-Site Exception** can be added to their CLIA certificate by selecting #1 under Section V on the CMS116 (*CLIA Application for Certificate*)

This option reads as follows (check the “yes” boxes as indicated below):

V. MULTIPLE SITES

Are you applying for a single site CLIA certificate to cover multiple testing locations?
If yes, complete the remainder of this section. **Select “yes”**

Indicate which of the following regulatory exceptions applies to your facility’s operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?
Select “yes”
- **Complete page 1** (select any other changes), and have the **lab director sign page 5** of the CM116 (CLIA Application for Certificate). This signature is required because the director is responsible for regulatory compliance at the other testing locations.
 - **Email and mail** the CMS116 to the CLIA office.

Email: CLIALAB@vdh.virginia.gov

Physical Address: VDH - Office of Licensure and Certification
9960 Mayland Drive-Suite 401
Henrico, Virginia 23233