



October 7, 2020

To: Nevada Department of Education

From: Bradley Waples, BS, MT (ASCP)- Phone: 775-430-0034 Email: bwaples@health.nv.gov

Nevada School System to Perform COVID-19 Point of Care (POC) Antigen Laboratory Testing

In an effort to address the COVID-19 pandemic, the Federal Government through the Centers for Medicare and Medicaid Services (CMS), is moving forward with securing and distributing COVID-19 testing supplies to the K through 12 school system. To take advantage of this testing capability, each participating school district will be required to have a state of Nevada laboratory license and a Federal CLIA (Clinical Laboratory Improvement Amendments) certificate.

School District Process for State Laboratory License and Federal CLIA Certificate:

1. Each school district in Nevada who chooses to participate in COVID-19 point of care testing will be required to obtain a state of Nevada lab license and a separate, but associated, license for each school that chooses to participate and a Federal CLIA certificate per School District before any schools within the district may perform the antigen POC testing.
2. Each participating school district will operate under one CLIA certificate number and a Nevada laboratory license number for the district with associated laboratory license numbers for each school under the district that chooses to participate
3. Each school within the participating district who will be performing COVID-19 testing will be issued an associated license.
 - o For example: if a district has ten schools who choose to perform COVID-19 point of care testing and that district's Nevada main laboratory license is 1200 EXL, each school within that district will be issued an associated license as follows: 1200-A EXL, 1200-B EXL, 1200-C EXL, etc.
4. Any personnel performing specimen collection or COVID-19 laboratory testing must meet the requirements of NAC 652.210(1). If the collection or testing personnel do not meet this requirement, they must obtain an Office Laboratory Assistant certificate, issued by the Division of Public and Behavioral Health's medical laboratory services unit. Personnel certificates may be obtained by applying through the Division's online licensing system: <https://nvdpbh.athent.com/>
5. Each participating school district and each school must have a laboratory director with overall responsibility for the testing and be the authorized provider identified as the individual ordering the COVID test and must meet the qualification requirement in NAC 652.397(1). The laboratory director is typically a physician (MD or DO), an Advance Practice Registered Nurse (APRN) or a Physician's Assistant (PA). There are no limitations regarding how many CLIA Waived and State exempt laboratories that a laboratory director may oversee; therefore, the school districts may choose to appoint a single laboratory director overseeing all participating school districts and schools in Nevada.
6. As with any initial laboratory, a required laboratory inspection by authorized Bureau of Health Care Quality and Compliance (HCQC) personnel must take place before any COVID-19 point of care testing may be initiated on humans. Regarding COVID-19 point of care testing in the school setting, HCQC staff will inspect only one laboratory per school district; all other participating schools within that district will need to follow the model of the laboratory that has been approved. Please also see the Exempt Laboratory Checklist for Schools which will be utilized for approval of the primary laboratory; all subsequent participating schools in that district must utilize this checklist as a template for compliance.

The application process for the schools will be executed manually through completion of the following forms and submitted documents. Once the forms are completed and required documents obtained, they must be submitted electronically to: Shannon Stodieck at sstodieck@health.nv.gov.

- The State of Nevada Exempt Laboratory Application (Email sstodieck@health.nv.gov for an application);
- Form CMS-116 (CLIA Application for Certification); (Available at: http://dpbh.nv.gov/Reg/MedicalLabs/dta/Forms/Medical_Laboratories_-_Forms/)
- Form – 1513 (Disclosure of Ownership and Control of Interest Statement; please fill these out by hand as they tend to auto-populate areas that are not correct); (Available at: http://dpbh.nv.gov/Reg/MedicalLabs/dta/Forms/Medical_Laboratories_-_Forms/)
- A driver's license or passport with a photo of the designated laboratory director;
- A list of each participating schools within the school district performing COVID-19 point of care testing to include: school name, address, and corresponding alphabetized letter as described in item (3.) above; and
- A list of all specimen collection testing personnel, their license or certificate number (MD, DO, APRN, PA or Office Laboratory Assistant) and the expiration date of each license or certificate.

Once all required documentation is received by Ms. Stodieck with HCQC, she will assign a Nevada laboratory license (and associated laboratory licenses to each school) and a CLIA number for each participating school district. Ms. Stodieck will also be available to assist with any questions related to the application process and may be reached at sstodieck@health.nv.gov or (775) 684-1042. After the Nevada laboratory license and CLIA number are issued for each application, the application is then assigned to an HCQC Inspector who will collaborate with the assigned school district to prepare and approve one location for COVID-19 point of care testing. All other schools within the approved, participating school district must use the completed Exempt Laboratory Checklist for Schools for the one approved location within the school district as a model for regulatory compliance.

Nevada laboratory licenses and CLIA certificates are eligible to any school that meets the statutory and regulatory requirements to become a medical laboratory licensed in Nevada.

- Schools who are non-profit, state, or federal schools should follow the application process noted above.
- For profit schools should submit an application to become an exempt laboratory by going to: <https://nvdpbh.aithent.com/>