COLORADO
Laboratory Services Division
Department of Public Health & Environment

Thank you for your interest in supporting the state's efforts to increase the testing capacity of COVID-19 samples during the pandemic.

A laboratory that performs testing on a human sample for the purposes of diagnosis, treatment of disease or assessment of health falls under the federal Clinical Laboratory Improvement Amendments (CLIA) requirements (42 CFR 493). These are the Federal Regulations for clinical diagnostic laboratories and may be found at the following website.

https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5

In order to perform COVID-19 tests, the laboratory must first obtain a CLIA certificate. If the laboratory already has a CLIA certificate, then a new one will not be required as a CLIA certificate is site-specific and covers the testing being performed at that physical location. Below is a link to the CMS-116 (CLIA application).

https://www.colorado.gov/pacific/cdphe/clia-clinical-laboratory-improvement-amendments

If samples are only going to be collected and sent to another CLIA certified laboratory for testing, a CLIA certificate is NOT required as that is considered specimen collection and processing, not testing.

There are four types of CLIA certificates and depending on the level of complexity of the test assigned by the FDA, dictates the type of CLIA certificate that is required. The categorizations for a test are either W-Waived, M-Moderate or H-High complexity. There are no lab director qualification requirements for a CLIA certificate of waiver. However there are lab director qualification requirements for a CLIA certificate of Compliance, or a CLIA certificate of Accreditation. The lab director qualification requirements differ depending on whether the test is M-Moderate or H-High complexity.

The FDA has implemented the Emergency Usage Authorization (EUA) for COVID-19 tests and a number of molecular and serological tests have been submitted by different manufacturers and given a complexity rating by the FDA. If your laboratory is looking to perform a test that is not listed, or if your laboratory is developing an in-house developed test, it will automatically be classified as H-High complexity.

A current listing of approved tests may be found at the following link. It is continuously being updated by the FDA, so it is advised to refer to this if a test is currently not listed.

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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Additional resources for laboratories performing COVID-19 testing may be found at the following link.

https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Adesc

In addition to performing the tests, Colorado requires that all positive and negative test results are reported to the Colorado Department of Public Health and Environment (CDPHE) by both the providers and labs to include the patient's demographics..

Below is detailed guidance regarding reporting. To ensure that we have all positive cases from your lab, you may reference our "Report a Disease" website for general reporting guidance and to find our ***NEW*** COVID reporting form.

A list of Reportable Conditions in Colorado is also available to ensure you are reporting all conditions required.

For COVID reporting:

If reporting by ELR, please send both positive and negative COVID results

If reporting by fax, please only report COVID positive results.

Reports can also be sent via encrypted email to: CDPHE_IDRP@state.co.us

Fax **COVID/all other non-STI disease** reports to: 303-782-0338

Fax **STI reports** to: 303-782-5393

All reports and specimens shall be accompanied by the following information:

- Name of disease or condition
- Patient's name
- Patient's date of birth, sex, race, ethnicity
- Patient's home address and phone
- Healthcare provider's name, address and phone number
- Laboratory information - Testing lab name, test name/type (PCR, IgM, etc), collection date, specimen type, result, and accession number

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As part of our efforts to understand the testing that is coming through to us, please answer the following questions:

1. On what date did you start COVID testing?
    a. What tests are you running? What date did you start each of these?
2. On what date did you start COVID reporting? To which states?
3. How many positive results for Colorado patients have you had in that time?
4. Have your already resulted positive COVID tests been reported to CDPHE?
5. Do you expect your testing volume for Colorado patients to increase over the next several months? How much?
6. Is your laboratory information system capable of generating an HL7 2.5.1 message?
7. Who are your primary clients/submitters?

For additional information or assistance, please contact the CLIA Program Manager, Jeff Groff at jeff.groff@state.co.us or at 303.692.3681.

Thank you.