NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

State Health Director Temporary Order to Report COVID-19 Diagnostic Tests
SL 2020-4, Sec. 4.10(a)(1) – Guidance

Background

On July 7 2020, the State Health Director issued a Temporary Order to Report COVID-19 Diagnostic Tests, pursuant to authority granted in GS 130A-141.1, that fulfills the requirements of SL 2020-4, Sec. 4.10(a)(1) and provides information necessary for surveillance of COVID-19. The Order requires healthcare providers and laboratories to report positive and negative COVID-19 diagnostic test results. Reports are directed to be made in accordance with this guidance.

Who is required to report?

- Physicians licensed to practice in the State
- Laboratories operating in the State
- Other health care providers who are licensed, certified, or credentialed to practice or provide health care services and who are ordering or conducting COVID-19 diagnostic testing in the State. This includes, but is not limited to, pharmacists, dentists, physician assistants, registered nurses, licensed practical nurses, advanced practice nurses, chiropractors, respiratory care therapists, and emergency medical technicians.

Health care providers, other than physicians, who submit specimens for COVID-19 diagnostic testing to a laboratory for processing will be deemed to have met the requirement to report the test results for those specimens, if the health care provider verifies that the laboratory will report those results and ensures that all patient data elements listed in the "Key Data Fields" section of this guidance are included on the lab order. This does not relieve health care providers of the requirement to report the results of diagnostic COVID-19 tests conducted by the provider (rather than submitted to a reporting laboratory).

Pursuant to GS 130A-135 and 10A NCAC 41A .0101, physicians are required to report all suspected and confirmed cases of COVID-19. However, physicians who submit specimens for COVID-19 testing to a laboratory for processing will be deemed to have met the requirement to report the negative test results of those specimens, if the physician verifies that the laboratory will report those results and ensures that all patient data elements listed in the "Key Data Fields" section of this guidance are included on the lab order. This does not relieve the physician of the requirement to report suspected and confirmed cases of COVID-19, including positive test results, to their local health department in accordance 10A NCAC 41A .0102. It also does not relieve the physician of the requirement to report the negative results of COVID-19 tests conducted by the physician (rather than submitted to a reporting laboratory).

What is required to be reported?

The Order requires the reporting of all COVID-19 diagnostic test results, both positive and negative. A COVID-19 diagnostic test is defined as a viral detection test and does not include antibody tests. The data elements that are required to be reported are listed in the section "Key Data Fields" below.

Method of Reporting

Pursuant to GS 130A-135 and 10A NCAC 41A .0101, physicians are required to report all suspected and confirmed cases of COVID-19, including positive test results, immediately in accordance with 10A NCAC 41A .0102. This mandatory reporting requirement is outside of the July 7, 2020 Temporary Order to Report and this guidance.

Physicians and other healthcare providers are required to report all other test results that will not be reported by a laboratory in accordance with this guidance within 24 hours of receiving the test result by telephone or secure fax to the local health director in the county or district where the patient resides. The local health department will follow up, as needed, to obtain additional information. The health department shall report the result within 24 hours to the Division of Public Health.

Laboratories are required to report electronically, either via Electronic Lab Reporting (ELR) or in accordance with the laboratory data automation process outlined below.

Laboratories currently sending positive COVID-19 test results via ELR through an automated Health Level Seven International (HL7) message are required to add negatives to this method of reporting.

For those laboratories not currently submitting ELR results, the COVID-19 Laboratory Data Automation (CLDA) process has been created to assist laboratory facilities in meeting this requirement. Unless otherwise set out in this guidance, laboratory facilities must initiate this process within seven (7) calendar days and complete this process within 30 calendar days of the date they begin to perform COVID-19 diagnostic testing or the date of the July 7, 2020 Temporary Order to Report, whichever is later. Until a laboratory has completed the data automation process, the laboratory is instructed to report COVID-19 test results by secure telefax to the appropriate local health department(s) or to the Division of Public Health. The secure telefax report must include the elements in the "Key Data Fields" section below.

Laboratory results should be reported daily by midnight. Any lab results that come in after 5pm may be reported by midnight the following day.

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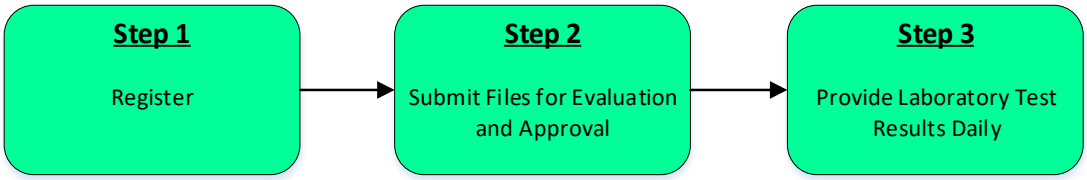
COVID-19 Laboratory Data Automation (CLDA) Process



Step 1 – Register for NCID and Complete the CLDA Registration Form

- **Register** for a Business NCID at https://ncid.nc.gov
  - Up to three individuals, who will submit files for your facility, can register for a Business NCID
  - Those individuals will format their unique Business NCID Username as CLDA-LabName-FirstInitialLastName **Example: CLDA-LABNAME-CGRANT**
  - NCIDs have a limit of 20 characters, which may require an abbreviation of your last name
- **Complete** the CLDA Registration Form
  (Requires basic fields: Address, NCID, CLIA number, test type, weekly expected testing)

Upon completion of registration, the facility can move to Step 2.

Step 2 – Submit Files for Evaluation and Approval

An email containing a CLDA Toolkit will be sent to the address provided by the facility in the CLDA Registration Form. The CLDA Toolkit contains guidance and terminology, a CSV data dictionary outlining the Key Data Fields below in greater detail and format, a CSV template and a sample CSV File. Instructions to securely send a properly formatted CSV file containing both COVID-19 positive and negative diagnostic laboratory results will be included in the email.

After the submission of a sample file, the CLDA team will evaluate the submission and provide feedback.

Upon approval of several successful sample files, the facility can move to Step 3.

Step 3 – Provide Laboratory Test Results Daily

An email will be sent (to the address provided by the facility in the CLDA Registration Form) with instructions to securely send the facility's completed COVID-19 diagnostic positive and negative laboratory test results daily. The facility will be contacted by the CLDA team if any errors are encountered with the file.

Once the facility has submitted several successful production files, the facility will no longer submit COVID-19 diagnostic results to the state or local health departments by any other means (e.g., fax, telephone).

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Extension Requests

Facilities that have low volume (less than 100 labs per week) and a low technology capability (no on-site technical support) may request an extension to the implementation timeline. To request an extension, the facility is directed to send an email for review to CLDA.SupportServices@dhhs.nc.gov and include:

- Reason for extension request with supporting documentation
- Current testing volume of positive and negative COVID-19 diagnostic results
- Expected timeline to provide all COVID-19 diagnostic results through the automation process

Key Data Fields

Facilities are required to collect and report on **all** fields listed below. Bold fields indicate elements whose absence may cause the file to be rejected. If a patient is unable or unwilling to provide required fields, these fields should be left empty. The CLDA Toolkit has formatting guidance for these fields.

U.S. Department of Health and Human Services (HHS) announced new guidance that specifies what additional data must be reported to HHS by laboratories along with Coronavirus Disease 2019 (COVID-19) test results by August 1, 2020.

Message Data	
COVID19_CSV_REC_TYPE	Required
Record Count	Required
Date/Time sent	Required
Message Control ID	Required
Patient Data	
Patient First Name	Required
Patient Last Name	Required
Patient Middle Name	If available
Patient Date of Birth	Required
Patient Social Security Number	If available
Patient Address	Required
Patient City	Required
Patient State	Required
Patient ZIP Code	Required by August 1, 2020
Patient County	Required
Patient Phone	Required
Patient Email	If available
Patient Sex	Required by August 1, 2020
Patient Race	Required by August 1, 2020
Patient Ethnicity	Required by August 1, 2020

Specimen/Test Data	
Specimen Collection Date	Required
Placer Specimen ID	Required
Accession ID	Required
Specimen Type	Required
Received Date	Required
Test Name	Required
Test LOINC Code	Required
Result	Required
Result Date	Required
Result Status	Required
Comment	Optional
Device Identifier	Required by August 1, 2020
Performing Lab Data	
Performing Lab Name	Required
CLIA Number	Required
Performing Lab Address	Required
Performing Lab Phone	Required
Ordering Facility Data	
Ordering Facility Name	Required
Ordering Facility Address	If available
Ordering Facility City	If available
Ordering Facility State	If available
Ordering Facility ZIP Code	If available
Ordering Facility Phone	If available
Provider Data	
Provider Last Name	Required by August 1, 2020
Provider First Name	Required by August 1, 2020
Provider NPI	Required by August 1, 2020
Provider Phone	If available
Provider Address	If available
Provider City	If available
Provider State	If available
Provider ZIP Code	Required by August 1, 2020
Patient MRN	If available
Ask on Order Entry (AOE)	
Symptomatic	Required by August 1, 2020
Symptom Onset Date	Required by August 1, 2020
First Test?	Required by August 1, 2020
Employed in Healthcare?	Required by August 1, 2020
Hospitalized?	Required by August 1, 2020
ICU?	Required by August 1, 2020

Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other setting)?	Required by August 1, 2020
Pregnant?	Required by August 1, 2020