NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NCDHHS Guidance for Reporting of COVID-19 Diagnostic Test Results
Updated: December 14, 2020

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 required healthcare providers and laboratories to report positive and negative COVID-19 diagnostic test results.

On September 15, 2020, the North Carolina Commission for Public Health adopted 10A NCAC 41A .0107 ("Rule .0107") under emergency procedures and simultaneously proposed to adopt 10A NCAC 41A .0107 under temporary procedures. Effective September 25, reports are required to be made in accordance with this Rule.

On December 14, 2020, the COVID-19 Positive Antigen Lab Test Report was included for laboratories and healthcare providers who do not have the required data in another format.

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 order 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.

What is required to be reported?

Results of all COVID-19 diagnostic test results must be reported, both positive and negative. A COVID-19 diagnostic test means any nucleic acid or antigen test that identifies SARS-CoV-2, the virus that causes COVID-19. This 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 – Laboratories

Per Rule .0107, each person in charge of a laboratory providing diagnostic service in this State shall report the results of all COVID-19 diagnostic tests to the Division of Public Health using electronic laboratory reporting ("ELR"). ***As defined in this Rule, "laboratory" includes any healthcare provider who performs testing in an on-site facility certified by the United States Department of Health and Human Services under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations, including facilities with a CLIA certificate of waiver.***

- 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 was created to assist laboratory facilities in meeting this requirement. Per Rule .0107, laboratories are required to submit a COVID-19 Laboratory Data Automation Registration form to the Division of Public Health within seven (7) days of the date the laboratory starts performing COVID-19 diagnostic testing and act in good faith to onboard to ELR by completing the CLDA process. The CLDA Registration form is available at https://slph.ncpublichealth.com/doc/NCCOVID-19LabDataAutomation-CLDA-ProcessIntroduction.pdf.

- Laboratories that complete fewer than 50 total COVID-19 diagnostic tests per week ("low-volume laboratories") may, but are not required to, onboard to ELR.

- Low-volume laboratories that choose not to onboard to ELR and laboratories that are in the process of onboarding to ELR through the CLDA process are required to:

    - Report the results of positive COVID-19 tests by secure telefax to the Division of Public Health at (919) 733-0490. The secure telefax report must include all elements in the "Key Data Fields" section below. The COVID-19 Positive Antigen Lab Test Report is available for laboratories that do not have the required data in another format.

    - Report the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the Division of Public Health through the Electronic COVID-19 Aggregate Test Reporting (eCATR) Process.

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

Method of Reporting – Healthcare Providers

Per Rule .0107, healthcare providers who order COVID-19 diagnostic testing in this State shall immediately report the results of all COVID-19 diagnostic tests by secure telefax to the local health director in the county or district where the patient resides. The elements required to be reported are set out in Subparagraph (e)(1) of Rule .0107. The COVID-19 Positive Antigen Lab Test Report is is available for healthcare providers who do not have the required data in another format.

Healthcare providers are also required to report the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the Division of Public Health through the Electronic COVID-19 Aggregate Test Reporting (eCATR) Process.

Healthcare providers who submit specimens for COVID-19 diagnostic testing to a laboratory for processing will be deemed to have met the Rule .0107 reporting requirements if the healthcare provider verifies that the laboratory that receives the specimens for testing will report those results and ensures that patient first and last

name, date of birth, address, county of residence, phone number, sex, race, ethnicity, and specimen collection date are included on the lab order. In this case, no further reporting by the healthcare provider is required by Rule .0107.

Note Regarding Physician Reporting

The reporting requirements contained in Rule .0107 are separate from the physician reporting requirements set out in GS 130A-135 and 10A NCAC 41A .0101. Physicians are required to report all suspected and confirmed cases of COVID-19 to their local health department in accordance with 10A NCAC 41A .0102.

Key Data Fields

Laboratories are required to collect and report on **all** fields listed below. Bold fields indicate elements whose absence may cause the file to be rejected in the CLDA process. The CLDA Toolkit has formatting guidance for laboratories for these fields.

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
Patient County	Required
Patient Phone	Required
Patient Email	If available
Patient Sex	Required
Patient Race	Required
Patient Ethnicity	Required
Specimen/Test Data	
Specimen Collection Date	Required
Placer Specimen ID	Required
Accession ID	Required
Specimen Type **Test Order Date**	Required Required
Received Date	Required
Test Name	Required

Test LOINC Code	Required
Result	Required
Result Date	Required
Result Status	Required
Comment	Optional
Device Identifier	Required
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
Provider First Name	Required
Provider NPI	Required
Provider Phone	If available
Provider Address	If available
Provider City	If available
Provider State	If available
Provider ZIP Code	Required
Patient MRN	If available
Ask on Order Entry (AOE)	
Symptomatic	Requested
Symptom Onset Date	Requested
First Test?	Requested
Employed in Healthcare?	Requested
Hospitalized?	Requested
ICU?	Requested
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)?	Requested
Pregnant?	Requested