**10A NCAC 41A .0107- Reporting of COVID-19 Diagnostic Test Results**

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| Agency: | North Carolina Commission for Public Health<br>Department of Health and Human Services<br>Division of Public Health<br>Epidemiology Section<br>Communicable Disease Branch |
| Rule Citation(s): | 10A NCAC 41A .0107 Reporting of COVID-19 Diagnostic Test Results |
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| Rulemaking Authority: | G.S. 130A-134<br>G.S. 130A-135<br>G.S. 130A-139<br>G.S. 130A-141.1<br>S.L. 2020-4, s. 4.10(a)(1)<br>P.L. 100-578<br>42 C.F.R. 493 |
| Impact Summary: | State Government: Yes<br>Local Government: No<br>Private Sector: Yes<br>Substantial Impact: Yes |

## Introduction and Purpose

COVID-19, a novel coronavirus, was identified as the cause of an emerging infectious disease outbreak in December 2019 in Wuhan, Hubei Province, China. This novel coronavirus causes respiratory illness ranging in severity from mild illness to death. As of April 7, 2021, over 131,837,500 confirmed cases and 2,862,600 deaths had been reported from 216 countries

worldwide,[1] over 30,596,830 cases and 554,420 deaths had been reported in the U.S.,[2] and over 924,810 cases and 12,212 deaths had been reported in North Carolina.[3] The North Carolina Division of Public Health is working closely with the Centers for Disease Control and Prevention (CDC) to monitor and respond to this pandemic in North Carolina.

Due to the widespread community transmission of this serious, infectious disease, testing is occurring in non-traditional environments, such as community-based testing sites. For this reason, reporting requirements need to be extended to other types of healthcare providers potentially involved in testing, such as nurses, pharmacists, and dentists. It is also imperative that public health officials receive not only positive tests results, but also negative test results, to better understand the prevalence of the disease in North Carolina.

To address this, the legislature enacted S.L. 2020-4 Sec. 4.10(a)(1) and the State Health Director issued a temporary order, pursuant to her authority under G.S. 130A-141.1, requiring healthcare providers and laboratories to report all COVID-19 diagnostic test results, both positive and negative, effective July 7, 2020. On September 15, 2020, the Commission for Public Health (CPH) adopted 10A NCAC 41A .0107 under emergency procedures and simultaneously proposed to adopt 10A NCAC 41A .0107 under temporary procedures to continue the reporting requirement. The temporary rule was adopted by CPH at its meeting on November 4, 2020. This proposed permanent rule would ensure the continuation of the requirement that healthcare providers and laboratories report all COVID-19 diagnostic test results, both positive and negative, to public health officials.

**Description of Proposed Rules**

Rule 10A NCAC 41A .0101, North Carolina's reportable diseases and conditions rule, was recently permanently amended, effective April 1, 2021, to require that physicians and laboratories report COVID-19 infections and infections causing death. The new requirements that are established under rule 10A NCAC 41A .0107 are therefore limited to: (1) the requirement that physicians and laboratories report negative test results to public health, (2) the requirement for other types of health care providers, who are not typically mandatory reporters, to report positive and negative COVID-19 diagnostic test results to public health, and (3) the requirement for laboratories to take action to onboard to electronic reporting methods for purposes of reporting COVID-19 diagnostic test results.

**Impact Analysis**

At present, the number of COVID-19 cases in North Carolina appear to be declining, which may be due to the increasing availability and administration of COVID-19 vaccines, advances in COVID-19 treatment, and the continuation of mitigation measures (such as wearing masks and social distancing); however, shifting conditions, as well as the emergence of variant strains of the virus, make it difficult to predict the course of the pandemic. At this time, over 11 million

[1] World Health Organization, "Coronavirus (COVID-19) Dashboard," available at: https://covid19.who.int/.
[2] United States Centers for Disease Control and Prevention, "COVID Data Tracker," available at: https://covid.cdc.gov/covid-data-tracker/#datatracker-home.
[3] North Carolina Department of Health and Human Services, "COVID-19 North Carolina Dashboard," available at: https://covid19.ncdhhs.gov/dashboard.

COVID-19 tests have been performed in North Carolina since the start of the pandemic.[4] Although it is challenging to project how many tests will be administered in the coming months, we expect that COVID-19 diagnostic testing will continue to play an important role in the COVID-19 pandemic response.

Given these challenges in projecting forward, for the purpose of this impact analysis the period of reference that is used is the time between September 25, 2020 (the date on which the emergency rule became effective) and February 28, 2021, a period of approximately 5 months. During that time, there were approximately 6,845,308 COVID-19 diagnostic tests performed and reported to public health in North Carolina. As set out in Table 1 below, of those 6,845,308 test results, approximately 10% were positive and 90% were negative. These figures are used to estimate the economic impact of the proposed rule on local government, state government, and the private sector. **We believe that the calcuations presented in this fiscal note likely represent a high-end estimate of the overall impact and that the actual costs may be lower.**

| **Table 1. COVID-19 Diagnostic Test Volume, Sep. 25, 2020 – Feb. 28, 2021** | | |
|---|---|---|
| Total Tests Performed | # (%) Positive | # (%) Negative |
| 6,845,308 | 695,345 (10%) | 6,149,963 (90%) |

Local Government Impact

The overall impact of rule 10A NCAC 41A .0107 on local government is expected to be very limited. We anticipate that this impact could stem from a slight increase in positive reports made to local health departments by providers who were not previously required to report COVID-19 diagnostic test results (e.g., pharmacists, dentists), under paragraph (e)(2) of the rule. However, the impact is expected to be very limited because the requirement to report is considered met if the provider verifies that the laboratory will report the result in accordance with the rule. With this provision to eliminate duplicative reporting, we expect that very few additional results with be reported to local health departments, thereby creating little to no economic impact on local government.

State Government Impact

The impacts to state government that result from rule 10A NCAC 41A .0107 include: (1) the cost of setting up a COVID-19 Laboratory Data Automation (CLDA) process for laboratories that do not have the capability to engage in electronic laboratory reporting (ELR) through an automated Health Level Seven International (HL7) message[5], (2) the cost associated with creating the electronic COVID-19 aggregate test reporting (eCATR) system, to be used until a laboratory onboards to electronic reporting, and (3) receipt and analysis of aggregate results submitted by healthcare providers through the eCATR online survey. As noted in Table 2 below, the development of the CLDA process and eCATR systems will be one-time costs to the state, whereas the use of temporary staff time to support these systems, provide technical assistance, and assist with data analysis and integration will be an ongoing cost.

[4] North Carolina Department of Health and Human Services, "NC DHHS COVID-19 Dashboard: Testing," last accessed April 8, 2021 and available at: https://covid19.ncdhhs.gov/dashboard/testing.

[5] North Carolina Department of Health and Human Services, "COVID-19 Laboratory Data Automation (CLDA) Process," available at: https://slph.ncpublichealth.com/doc/NCCOVID-19LabDataAutomation-CLDA-ProcessIntroduction.pdf

*COVID-19 Laboratory Automation (CLDA)*

Pursuant to 10A NCAC 41A .0107(b), laboratories are required to submit COVID-19 diagnostic test results to DPH using ELR. To accommodate laboratories who do not have ELR HL7 capabilities, DPH established the CLDA process. Laboratories can begin the ELR onboarding process and satisfy the requirement of Paragraph (b) of the rule if they submit a COVID-19 Laboratory Data Automation Registration form to DPH and comply with the process described in Subparagraph (c)(1) of the rule. The CLDA process was developed internally by DPH employees across a period of approximately two months by 3.5 epidemiologists (three working full-time and one working part-time on CLDA) and 1 full-time, temporary Rhapsody programmer hired (at $80/hour) to support CLDA development. The costs incurred for the use of these employees' time is described in Table 2 below. The costs associated with the 3.5 epidemiologists' time is an opportunity cost to DPH.

When labs onboard to CLDA, they are required to register and submit test files to DPH using the CLDA process. The test files are reviewed by DPH staff, who identify errors in the file format, conduct error reconciliation, and provide technical assistance and education back to the labs to ensure that the next file is submitted correctly. Once labs are onboarded to CLDA, DPH staff continue to provide the same error reconciliation, technical assistance, and real-time troubleshooting support services, which requires a significant amount of time.

As a result, during the period of reference (September 25, 2020 to February 28, 2021), DPH hired several temporary staff to support this new area of work related to CLDA. DPH hired four informaticians (full-time at an average of $30/hour); three programmers to support Rhapsody, the data integration software that DPH uses to pull reported test result information into our surveillance system (all full-time at $80/hour); and one business analyst, who provides support with troubleshooting and assisting laboratories during the onboarding process (full-time at $55/hour). This team of new temporary hires also provides support for operationalizing the eCATR system, which is discussed below. The costs associated with hiring these temporary staff members is described in Table 2 below.

*Electronic COVID-19 Aggregate Test Reporting (eCATR)*

While laboratories work to onboard to ELR, they fulfill the requirements of the rule by submitting aggregate COVID-19 diagnostic test results through eCATR, an online survey platform. Laboratories that conduct a low volume of COVID-19 diagnostic tests (fewer than 50 tests per week) may exclusively use eCATR to report results to DPH and are not expected to eventually onboard ELR. eCATR was developed for DPH by a vendor and also required the purchase of several software licenses. The total cost of developing and standing up eCATR was approximately $1,297,469.83. As with CLDA reporting, operationalizing the eCATR system requires time spent by DPH staff who provide technical assistance, programming expertise, and support for the receipt and analysis of aggregated results submitted through eCATR. This work is carried out by the same team of new hires that provides support for the CLDA process. These costs to state government are reflected in Table 2 below.

There is a second requirement that laboratories must meet while onboarding to ELR, which is to fax positive results to DPH. However, processing these faxed results is not an additional cost of

this rule because, under 10A NCAC 41A .0102, if a laboratory is not reporting electronically, it is required to report positive results to DPH by mail, phone, or telefax. For that reason, processing these faxes is not a new cost to the state.

| **Table 2. State Government Impact** | | | |
|---|---|---|---|
| **2A. CLDA and eCATR Development and Stand Up (One-Time Costs)** | | | |
| Amount Paid to Vendor to Develop and Operationalize eCATR and Software Licenses | | Total Cost | |
| $1,297,469.83 | | $1,297,469.83 | |
| Number of Epidemiologists Assigned to CLDA Development and Stand Up | Total Number of Staff Hours Worked (40 hrs/wk) in 2 Month Period per 1 Staff Member | Hourly Rate of State Public Health Epidemiologist[6] | Total Cost |
| 3.5 | 320 | $46.31 | $51,867.20 |
| Number of Temporary Rhapsody Programmers Hired to Support CLDA Development and Stand Up | Total Number of Staff Hours Worked (40 hrs/wk) in 2 Month Period per 1 Staff Member | Hourly Rate of Temporary Rhapsody Programmer | Total Cost |
| 1 | 320 | $80 | $25,600 |
| **2B. Temporary Staff to Support CLDA and eCATR (Ongoing Cost- 5 Month Projection)** | | | |
| Number of Temporary Informaticians Hired | Total Number of Staff Hours Worked (40 hrs/wk) in 5 Month Period | Hourly Rate of Temporary Informatician | Total Cost |
| 4 | 800 | $30 | $96,000 |
| Number of Temporary Rhapsody Programmers Hired | Total Number of Staff Hours Worked (40 hrs/wk) in 5 Month Period | Hourly Rate of Temporary Rhapsody Programmer | Total Cost |
| 3 | 800 | $80 | $192,000 |
| Number of Temporary Business Analysts Hired | Total Number of Staff Hours Worked (40 hrs/wk) in 5 Month Period | Hourly Rate of Temporary Business Analyst | Total Cost |
| 1 | 800 | $55 | $44,000 |
| Total One-Time Costs to State Government ..... $1,374,937.03<br>Total Ongoing Costs to State Government (5 Month Projection) ..... $332,000.00<br>**Total Cost to State Government ..... $1,706,937.03** | | | |

[6] According to the North Carolina Office of State Human Resources (NC OSHR), the salary schedule grade of a public health epidemiologist is GN 12. The midpoint salary for GN 12 position is $63,552. Using NC OSHR's benefits calculator tool, the total annual compensation (which includes the value of benefits) for an employee earning this salary would be $96,335.13, which is the figure used to calculate an hourly rate. This value does not take into consideration number of years of state service, which could inform the value of benefits.

Costs to state government have been supported by federal funding to respond to the COVID-19 pandemic.

Private Sector Impact

*Providers*

Pursuant to 10A NCAC 41A .0107, some providers who have not historically had to report COVID-19 diagnostic test results will now be required to do so under the rule (e.g., pharmacists, nurses, dentists); however, the rule allows these providers' reporting obligations to be satisfied if a laboratory will report the test result as set forth under the rule. Many of the providers included in this cohort who are newly required to report under 10A NCAC 41A .0107 use outside laboratories to run COVID-19 diagnostic tests. Consequently, most of the results of the COVID-19 diagnostic tests that these providers offer to their patients end up being submitted to public health by laboratories rather than by the providers themselves.

In addition, there are a number of providers who may be treated as laboratories under the rule for reporting purposes because, by virtue of offering a point-of-care test under a Clinical Laboratory Improvement Amendments (CLIA) waiver, they are a CLIA certified laboratory. At this time, data is not available on the number of providers that this impacts; however, based on the experiences of DPH staff and communications with our provider partners across the state, we expect this number to be small and will fold this impact into the discussion of laboratories.

*Laboratories*

Laboratories were already required to report positive COVID-19 diagnostic test results under rule 10A NCAC 41A .0101; therefore, the main costs to the private sector that are expected to stem from the permanent adoption of 10A NCAC 41A .0107 are: (1) the cost of reporting negative COVID-19 diagnostic test results to DPH; and (2) the cost of onboarding to CLDA, if not already reporting using the HL7 ELR reporting method, and utilizing the eCATR survey during the onboarding process.

Rule 10A NCAC 41A .0107 requires that laboratories take action to begin onboarding to ELR for reporting COVID-19 diagnostic test results to DPH. Many laboratories in North Carolina are already set up to use an HL7 ELR reporting method, which facilitates their reporting of all reportable diseases and conditions in rule 10A NCAC 41A .0101 (not just COVID-19). This new rule is not expected to have a fiscal impact on these laboratories, as they already have required technology in place that can automatically send negative, as well as positive, test results.

For laboratories without HL7 capacity, DPH established a COVID-19 Laboratory Data Automation (CLDA) Process to onboard laboratories to ELR. The process of onboarding under the CLDA process includes the following costs: (1) time spent by laboratory staff to register with CLDA and send test files as part of the onboarding process and (2) generating files to submit to DPH using CLDA on a daily basis. As noted in Table 3 below, the registration and onboarding process will be a one-time cost to laboratories, whereas the generation and submission of data files on a regular basis will be an ongoing cost.

The CLDA onboarding process involves two key steps that laboratories must take: first, completing and submitting the lab's registration information (a one-time process that takes

approximately 15 minutes to complete) and second, generating and submitting test files to ensure that the file format that the lab is using is correct and that the data in the file can be successfully integrated into DPH's public health surveillance systems. According to DPH program staff who provide support to labs during the onboarding process, the amount of times that it takes a lab to generate the first test files can vary, and labs may have to continue to generate and resubmit new files multiple times before the process is perfected and they are ready to begin submitting real data. Our DPH program staff estimate that a lab, on average, may spend 10 hours, one time, on this component of the CLDA onboarding process.

Registering for CLDA and generating test files could be completed by a variety of laboratory employees, whose salaries could vary significantly; however, based on the experience of DPH staff, and for the purpose of this impact analysis, we have assumed that the individuals overseeing the CLDA onboarding process are frequently laboratory managers. The average salary of a laboratory manager in North Carolina is approximately $68,000.[7] The costs to laboratories associated with onboarding to CLDA are reflected in Table 3 below.

Once the laboratory has been onboarded to the CLDA process, the lab can use CLDA to submit its test results to DPH. Rule 10A NCAC 41A .0107 requires that laboratories report the results of COVID-19 diagnostic tests within 24 hours of receipt of the results. Although it is possible that some labs will have days when they have no test results to report, for the purpose of this impact analysis we have assumed that labs will have results every day that must be reported. Once a lab is onboarded to CLDA, the amount of time it takes to generate a daily data file will vary across labs: some labs may automate the file generation process, whereas others will use a more manual process that takes more time. Based on the experience of our DPH program staff and their communications with our laboratory partners, we expect that, on average, it would take approximately 20 minutes to generate and submit a file using the CLDA process.

This means that a staff person at each of the 925 CLIA-certified labs that were onboarded to the CLDA process during the period of reference (September 25, 2020 to February 28, 2021) would spend approximately 20 minutes per day generating and submitting the data file containing the COVID-19 diagnostic test results to DPH using CLDA. For the purpose of this impact analysis, we continue to assume that laboratory managers will most often be the ones who conduct this reporting. The costs associated with regular reporting of COVID-19 diagnostic test results through CLDA are reflected in Table 3 below.

Until such time as a laboratory onboards under the CLDA process, the laboratory is required to report positive results by secure telefax and aggregate positives and negatives through the eCATR survey. Notably, under 10A NCAC 41A .0102, if a laboratory is not reporting electronically, it is required to report positive results to DPH by mail, phone, or telefax, so the requirements of paragraph (c)(2)(A) are not new. For that reason, the main impact to laboratories, while going through the CLDA process, is the reporting of aggregates through eCATR.

[7] Based on information available at www.indeed.com, which uses self-reported salaries to estimate average salaries for positions in specific geographic areas. Although this is an imperfect method of estimating average lab manager salaries in the private sector, this figure is consistent with average North Carolina lab manager salaries listed on comparable websites, including www.glassdoor.com and www.ziprecruiter.com.

For the time period of reference for this impact analysis- September 25, 2020 through February 28, 2021- approximately 97.8% of the 6,845,308 COVID-19 diagnostic test results (negative and positive) that were reported to public health were reported electronically. This indicates that, in comparison to the 925 labs onboarded to CLDA during that time period and the large number of labs already reporting using ELR, very few laboratories were using the eCATR/telefax alternative permitted under paragraph (c)(2). During this time period, only 498 laboratories used eCATR.

For the laboratories using eCATR, the process of reporting aggregate results is expected to require a small amount of time, as the process entails completion of a brief online survey. Based on familiarity with the eCATR survey tool, our staff estimate that reporting test results through eCATR takes approximately 5 minutes. Reporting in aggregate through the eCATR online survey also does not have to be done by someone with a specific license, position, or set of skills. Laboratories may choose to have results submitted through eCATR by a range of employees, whose hourly salaries could vary significantly. For the purpose of this impact analysis and for consistency across our calculations, we continue to assume that laboratory managers will most often be the laboratory staff who conduct this reporting.

Rule 10A NCAC 41A .0107 requires that laboratories report the results of COVID-19 diagnostic tests within 24 hours of receipt of the results. Although it is possible that some labs will have days when they have no test results to report, for the purpose of this impact analysis and for consistency across our calculations, we have assumed that labs will have results every day that must be reported. This means that a staff person at each of the 498 labs that were reporting through eCATR during the period of reference (September 25, 2020 to February 28, 2021) would spend approximately 5 minutes per day submitting COVID-19 diagnostic test results to DPH using eCATR. These costs are reflected in Table 3 below.

| **Table 3. Private Sector Impact** | | | |
|---|---|---|---|
| **3A. CLDA Onboarding Process (One-Time Cost)** | | | |
| Number of Labs Onboarded to CLDA, Sept. 25, 2020 – February 28, 2021 | Time in Hours of Work by 1 Lab Manager to Complete CLDA Onboarding | Estimated Hourly Rate of Lab Manager | Total Cost |
| 925 | 10.25 | $32.70 | $310,036.86 |
| **3B. CLDA and eCATR Reporting (Ongoing Costs- 5 Month Projection)** | | | |
| Number of Labs Onboarded to CLDA, Sept. 25, 2020 – February 28, 2021 | Time in Hours of Work by 1 Lab Manager to Submit Test Results via CLDA, in 5 Month Period | Estimated Hourly Rate of Lab Manager | Total Cost |
| 925 | 42 | $32.70 | $1,270,395 |
| Number of Labs Reporting through eCATR, Sept. 25, 2020 – February 28, 2021 | Time in Hours of Work by 1 Lab Manager to Submit Test Results via eCATR, in 5 Month Period | Estimated Hourly Rate of Lab Manager | Total Cost |

| | | | |
|---|---|---|---|
| 498 | 4.66 | $32.70 | $75,886.24 |
| Total One-Time Costs to Private Sector …..……. $310,036.86<br>Total Ongoing Costs to Private Sector (5 Month Projection) ……..……. $1,346,281.24<br><br>**Total Cost to Private Sector ……..…….. $1,656,318.10** | | | |

**Summary**

The permanent adoption of 10A NCAC 41A .0107 will aid the State in assessing the impact of COVID-19 in North Carolina. Specifically, robust surveillance data helps us better understand trends, identify higher-risk subgroups, and implement timely and effective control measures, which is expected to translate to reduced risk of transmission of COVID-19 and better health for North Carolina's residents. The rule is expected to result in an economic impact to state government of 1,706,937.03, a total expense that stems from the creation, operationalization, and support of the eCATR system and CLDA process. There is minimal expected impact to local government. The economic impact to the private sector is estimated to be $1,656,318.10, which stems from the costs of laboratory staff time used to onboard to CLDA, to report results by eCATR during the onboarding process, and eventually to submit regular data files containing test results through CLDA. Total impacts are described in Table 4 below.

| **Table 4. Total Impact** |
|---|
| *Total One-Time Costs to State Government ……. $1,374,937.03*<br>*+ Total Ongoing Costs to State Government (5 Month Projection) ….. $332,000.00*<br>**Total Impact to State Government ……..…… $1,706,937.03** |
| **Total Impact to Local Government …….. Minimal** |
| *Total One-Time Costs to Private Sector ……. $310,036.86*<br>*+ Total Ongoing Costs to Private Sector (5 Month Projection)……. $1,346,281.24*<br>**Total Impact to Private Sector ……. $1,656,318.10** |
| **Total Impact …..……... $3,363,255.13** |

**Substantial Economic Impact: Alternatives**

Pursuant to GS 150B-21.4(b2)(5), when an agency concludes its analysis and determines that the proposed rules will have a substantial economic impact[8], the agency shall include in its fiscal note a description of at least two alternatives to the proposed rules that were considered by the agency and rejected.

S.L. 2020-4, section 4.10(a)(1), which became effective on May 4, 2020, instructed the Department of Health and Human Services to "require each person in charge of a laboratory providing diagnostic service in this State and any other health care provider licensed in this State that provides diagnostic service to report the results of all COVID-19 testing" to the Department. The amendments to rule 10A NCAC 41A .0107 fulfill this requirement.

One alternative to the current framework would have been to allow laboratories to submit results in many ways (phone, telefax, email, and ELR) and not mandate electronic reporting. However, processing test results reported through these multiple methods would have required significant

[8] "Substantial economic impact" is defined at GS 150B-21.4(b1) as "an aggregate financial impact on all persons affected of at least one million dollars ($1,000,000) in a 12-month period."

staff time and been prohibitively expensive, as well as caused delays in integrating and analyzing data needed for critical public health pandemic mitigation work. In contrast to the speed with which electronically reported information can be sent, received, and integrated, this alternative approach would have required manual review and entry of test results, which would slow DPH's analysis and hinder quick assessment and response to trends.

A second alternative approach would have been to require the reporting of aggregate results only. Relying solely on aggregate data, however, has its limitations, and would impede DPH from generating a nuanced view of the pandemic and being able to timely identify outbreaks and clusters of COVID-19.

For the reasons described above, these alternative approaches were not pursued.

## Appendix: Proposed Rule Text

**10A NCAC 41A .0107 REPORTING OF COVID-19 DIAGNOSTIC TEST RESULTS**

(a) For purposes of this Rule, the following definitions shall apply:

(1) "COVID-19 diagnostic test" means any nucleic acid or antigen test that identifies SARS-CoV-2, the virus that causes COVID-19.

(2) "Electronic laboratory reporting" means the automated messaging of laboratory reports sent to the Division of Public Health using a machine-readable electronic communication protocol.

(3) "Healthcare provider" means a healthcare provider as defined in G.S. 130A-476(g).

(4) "Laboratory" means a facility that performs testing on specimens obtained from humans for the purpose of providing information for health assessment and for the diagnosis, prevention, or treatment of disease and is certified by the United States Department of Health and Human Services under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations. This definition includes a healthcare provider who performs testing in an on-site facility that meets these requirements.

(b) 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. For purposes of COVID-19, a novel coronavirus under Rule .0101(c)(1) of this Section, the required method of reporting set out in Rules .0101(c) and .0102(d)(3) of this Section shall not apply. The report shall include all of the elements required to be reported under the United States Department of Health and Human Services, laboratory data reporting guidance, which is hereby incorporated by reference, including any subsequent amendments and editions, and available free of charge at https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.

(c) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory:

(1) submits a COVID-19 Laboratory Data Automation Registration form to the Division of Public Health and acts to onboard to electronic laboratory reporting. This form shall be submitted within seven calendar days of the date the laboratory starts performing COVID-19 diagnostic testing and shall contain the following elements:

(A) the name, address, phone number, and CLIA number of the laboratory;

(B) the name, address, and phone number of the person in charge of the laboratory or that person's designee;

(C) the type of test performed, testing capacity, and whether the laboratory will use a third-party laboratory to perform part or all of the testing; and

(D) if the laboratory will use a third-party laboratory to perform part or all of the testing, the information in Subparagraphs (c)(1)(A)-(B) for the third-party laboratory; and

(2) until onboarding to electronic laboratory reporting is complete:

(A) reports the results of positive COVID-19 diagnostic tests to the Division of Public Health, including all elements required in Paragraph (b) of this Rule, by telefax; and

(B) reports 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 an online survey available at: https://files.nc.gov/covid/documents/eCATR-Reference-Guide.pdf.

(d) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory that completes fewer than 50 total COVID-19 diagnostic tests per week submits results as set out in Subparagraph (c)(2) of this Rule.

(e) Healthcare providers who order COVID-19 diagnostic testing in this State shall:

(1) report the results of positive COVID-19 diagnostic tests by telefax to the local health director in the county or district where the patient resides. The report shall contain:

(A) patient first and last name, date of birth, address, county of residence, phone number, sex, race, and ethnicity;

(B) provider name, address, phone number, and NPI;

(C) the specimen collection date, the test order date, and the test result date;

(D) the test result; and

(E) all other available elements required in Paragraph (b) of this Rule; and

(2) 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 an online survey.

(f) The requirements set forth in Paragraph (e) of this Rule shall be considered met if a healthcare provider:

(1) verifies that the laboratory that receives the specimen for testing will report the test result in accordance with Paragraph (b) of this Rule; and

(2) includes patient first and last name, date of birth, address, county of residence, phone number, sex, race, ethnicity, and specimen collection date on the lab order.

(g) The requirement for healthcare providers to report COVID-19 diagnostic test results, as set out in Paragraph (e) of this Rule, is separate from the requirement for physicians to report suspected infections of COVID-19, a novel coronavirus, including positive COVID-19 diagnostic test results, in accordance with G.S. 130A-135 and Rules .0101(a) and .0102(a) of this Section.

(h) Laboratories and healthcare providers who are required to report under this Rule shall report positive COVID-19 diagnostic test results immediately upon receiving the result and negative COVID-19 diagnostic test results within 24

hours of receiving the result. Results reported to a local health department under this Rule shall be forwarded to the Division of Public Health within 24 hours of receipt by the local health department.

*History Note:* *Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141; 130A-141.1; S.L. 2020-4, Sec. 4.10(a)(1); P.L. 100-578; 42 C.F.R. 493;*
*Emergency Adoption Eff. September 25, 2020;*
*Temporary Adoption Eff. December 1, 2020.*