

## Fiscal Note for Permanent Amendment of 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-139<br>G.S. 130A-141<br>G.S. 130A-141.1  |
| Impact Summary:       | State Government: No<br>Local Government: No<br>Private Sector: Yes<br>Substantial Impact: No   |

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### 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 1, 2022, over 486 million confirmed cases and 6.1 million deaths had been reported worldwide,<sup>1</sup> with over 79 million cases and over 977,000 deaths reported in the U.S.,<sup>2</sup> and over 2.6 million cases and over 23,000 deaths reported in North Carolina.<sup>3</sup> The North Carolina Division of Public Health is working

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<sup>1</sup> World Health Organization, "Coronavirus (COVID-19) Dashboard," available at: <https://covid19.who.int/>.

<sup>2</sup> United States Centers for Disease Control and Prevention, "COVID Data Tracker," available at: <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

<sup>3</sup> North Carolina Department of Health and Human Services, "COVID-19 North Carolina Dashboard," available at: <https://covid19.ncdhhs.gov/dashboard>.

closely with the Centers for Disease Control and Prevention (CDC) to monitor and respond to this pandemic in North Carolina.

To better understand the impact of COVID-19 on North Carolina, 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. The permanent rule was adopted by CPH on August 4, 2021 to 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.

Since this rule was permanently adopted in August 2021, the COVID-19 pandemic has continued to evolve. Immunity resulting from vaccination and infection, combined with new options for treatment and preventive measures, such as social distancing, masking, and improved ventilation in buildings, has offered increased protection from serious illness and death due to COVID-19. Additionally, treatments are now available for those at higher risk of severe disease and there is a robust supply of testing and personal protective equipment.. In turn, the public health response has shifted, including changes in the use of certain data and metrics to inform public health control measures. Federal guidance on COVID-19 data collection for public health surveillance was modified in March 2022 to end the reporting of negative COVID-19 antigen test results, which are no longer necessary to develop key metrics for monitoring COVID-19 and informing the pandemic response. Rule 10A NCAC 41A .0107 is proposed for permanent amendment to align the requirements for reporting COVID-19 diagnostic test results with these updates to federal guidance and current best practices at this stage in the pandemic.

### **Description of Proposed Rule Changes**

Rule 10A NCAC 41A .0101, North Carolina's reportable diseases and conditions rule, requires that physicians and laboratories report COVID-19 infections and infections causing death. Rule 10A NCAC 41A .0107, as it currently exists in the administrative code, builds on Rule .0101 by requiring: (1) physicians and laboratories to also report negative diagnostic test results to public health; (2) other types of healthcare providers, who are not typically mandatory reporters, to report positive and negative COVID-19 diagnostic test results to public health; and (3) laboratories to take action to onboard to electronic reporting methods for purposes of reporting COVID-19 diagnostic test results.

Rule 10A NCAC 41A .0107 is proposed for amendment to align COVID-19 diagnostic test result reporting with federal requirements and to reflect current best practices at this stage in the pandemic. Specifically, Paragraph (b) of the rule is amended to require reporting of COVID-19 diagnostic testing results in accordance with guidance issued by the United States Department of Health and Human Services (US DHHS). This guidance, which was already referenced in the rule for the purpose of identifying required data fields for test result reporting, establishes reporting requirements based on the type of entity that is conducting the testing and the type of test. Additionally, Subparagraph (c)(2)(B), which required aggregate reporting of positive and negative test results for laboratories that have not onboarded to electronic reporting, has been removed.

The result of these changes to the rule language is that the reporting of negative COVID-19 antigen test results will no longer be required from any type of entity conducting testing. Positive and negative results generated from polymerase chain reaction (PCR) testing will still be reportable. This change is expected to result in an impact and is discussed further in the Impact Analysis section of this fiscal note. Aligning more closely with federal guidance will ensure that North Carolina is able to continue responding to shifts in the COVID-19 pandemic in a nimble and timely manner that reflects national standards and best practices.

Rule 10A NCAC 41A .0107 also established reporting requirements for healthcare providers who are not typically mandatory reporters, such as pharmacists, dentists, physician assistants, registered nurses, licensed practical nurses, advanced practice nurses, chiropractors, respiratory care therapists, and emergency medical technicians. Paragraphs (e)-(g), which pertain to the reporting of COVID-19 diagnostic test results by healthcare providers, have been removed. Under both the existing and proposed rule language, many healthcare providers fall under the definition of a “laboratory,” by operating under a CLIA waiver, and are subject to the laboratory reporting requirements.

The removal of paragraphs (e)-(g) only affects healthcare providers that do not fall under the definition of a laboratory. These entities send specimens to outside laboratories for testing. Under Paragraph (f), these healthcare providers were not required to report COVID-19 diagnostic test results directly to public health officials when they confirmed that those results were already reported to public health by the laboratory that received the specimen. Based on existing data and our experience, the majority of these healthcare providers deferred to laboratories for reporting test results. Following the removal of Paragraphs (e)-(g) of this rule, these healthcare providers may be minimally impacted insofar as they will no longer need to confirm with laboratories that test results have been reported in accordance with the rule.

The text of the proposed rule has been included in the appendix.

### Impact Analysis

As of March 31, 2022, over 27 million COVID-19 diagnostic test results have been reported in North Carolina. For the purpose of this fiscal note, test result data from the most recent quarter, which ran from January 1, 2022, through March 31, 2022, is being used. This three-month period is representative of potential future stages of the COVID-19 pandemic: there were both high and low incidence periods in this time interval, which coincide with the peak and decrease of the Omicron wave, and the circumstances are as current as possible with regard to immunity, availability and use of vaccines and antiviral treatment, and testing protocols. A total of 5,123,358 COVID-19 diagnostic test results were reported to public health during this quarter, as set out in Table 1.

| <b>Table 1. COVID-19 Diagnostic (PCR and Antigen) Test Volume, January 1, 2022 – March 31, 2022</b> |                          |                          |
|---|--------------------------|--------------------------|
| Tests Performed   | # (%) Positive           | # (%) Negative           |
| PCR Tests   | 833,292 (20.7%)          | 3,192,098 (79.3%)        |
| Antigen Tests   | 188,336 (17.2%)          | 909,632 (82.8%)          |
| <b>Total</b>  | <b>1,021,628 (19.9%)</b> | <b>4,101,730 (80.1%)</b> |

### Local Government Impact

The overall impact of this amendment on local government is expected to be very limited. The local health department could see a slight decrease in positive reports received from healthcare providers under the current Paragraph (e)(1), which is proposed for deletion. However, as discussed above, the requirement to report under the existing rule is considered met if the provider verifies that the laboratory will report the result in accordance with the rule and most providers are deferring to the laboratory to report. For this reason, these changes are expected to result in little to no economic impact on local government.

### State Government Impact

The area of state government that is most directly involved in the routine collection and management of COVID-19 test result data is the Division of Public Health, Epidemiology Section. This team is not expected to be impacted by the amendment to rule 10A NCAC 41A .0107, except for minor cost savings that may arise from no longer having to save and store negative COVID-19 antigen test result data.

### Private Sector Impact

For the private sector, the change to 10A NCAC 41A .0107 is expected to result in a cost savings to entities designated as laboratories under the rule, as laboratories will no longer be required to report negative COVID-19 antigen test results. The rule requires laboratories to onboard to electronic reporting. Once onboarded, electronic reporting is an automated process requiring little active staff time. For that reason, this change will primarily impact laboratories who are still in the process of onboarding to electronic reporting. Under the current rule, these laboratories are required to fax positive results and report aggregate positive and negative results through the electronic COVID-19 aggregate test reporting (eCATR) survey (also known as the Laboratory Volume Survey or LVS). The proposed rule eliminates this mandatory aggregate reporting.

A total of 216,111 negative antigen test results were received through eCATR between January 1, 2022 and March 31, 2022. For the laboratories using eCATR, the reporting of aggregate results typically requires a small amount of time, as the process entails completion of the brief online survey. Based on our familiarity with the eCATR tool and feedback from industry partners over the past year, our staff estimate that reporting test results through eCATR takes approximately 5 minutes. Reporting in aggregate through eCATR 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. Based on our experience, and for the purpose of this fiscal note and consistency across our calculations, our analysis assumes that laboratory managers are the individuals who conduct reporting via eCATR. The average salary of a laboratory manager in North Carolina is approximately \$68,000.<sup>4</sup> This annual salary translates to an hourly pay rate of \$32.70.

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 laboratories had days when they had no test results to report, for the purpose of this fiscal note and consistency across our calculations, we have assumed that laboratories obtained results every day that had to be

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<sup>4</sup> Based on information available at [www.indeed.com](http://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](http://www.glassdoor.com) and [www.ziprecruiter.com](http://www.ziprecruiter.com).

reported. There were 13 weeks during the time period that runs from January 1, 2022 to March 31, 2022 and our data shows that 598 facilities submitted test results using eCATR during that time. Our calculation of the costs associated with reporting results via eCATR, as set forth in Table 2 below, assumes a five-day workweek for each of the 13 weeks or 65 instances of reporting per laboratory during a quarter.

| <b>Table 2. Cost Savings to Private Sector for eCATR Submission of COVID-19 Diagnostic Test Results, January 1, 2022 - March 31, 2022</b> |  |                                  |  |   |
|---|--|----------------------------------|--|---|
| Reporting Instances   | Time Spent per Laboratory per Reporting Instance | Number of Reporting Laboratories | Quarterly (3 Month) Cost Savings at Hourly Rate of \$32.70 | Annual Cost Savings at Hourly Rate of \$32.70 |
| 65  | 5 mins (.083 hours)                              | 598                              | \$109,159.92   | \$436,639.67                                  |
| <b>Total</b>  |  |                                  | <b>\$109,159.92</b>  | <b>\$436,639.67</b>                           |

As shown in Table 2, removal of the aggregate reporting requirement is estimated to have a cost savings to laboratories of \$109,159.92 per quarter or \$436,639.67 per year.

### Summary

The proposed changes to rule 10A NCAC 41A .0107 reflect the evolution of the COVID-19 pandemic and, subsequently, shifts in best practices for using certain data in public health surveillance. At this stage in the pandemic, it is no longer necessary for public health officials to collect negative COVID-19 antigen test results, as this data is no longer included in key metrics used to monitor and inform the COVID-19 response. This change is reflected in the recently updated US DHHS guidance, which the amended rule incorporates by reference as the standard for COVID-19 diagnostic test result reporting. Aligning the rule with federal guidance will enable North Carolina’s reporting requirements to update in real-time as the federal guidance is amended to address shifts in the COVID-19 pandemic, which is necessary for a timely and effective public health response.

There is little to no impact expected for local or state government as a result of the changes to this rule. There is a modest cost saving expected for the private sector, primarily for entities classified as laboratories under the rule who do not report electronically. These laboratories are estimated to see a total annual cost savings of approximately \$436,639.67 as a result of no longer being required to manually report aggregate results to public health officials under the amended rule.

## Appendix 1

### 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)(1).
- (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) at P.L. 100-578 and implementing regulations at 42 C.F.R. 493, which are hereby incorporated by reference, including any subsequent amendments or editions, and available free of charge at <https://www.congress.gov/public-laws/> and <http://ecfr.gov/>, respectively. 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~~ Reports shall be made in alignment with the requirements for laboratories by entity and type of testing and minimum data elements as set forth in ~~shall include all of the elements required to be reported under~~ the United States Department of Health and Human ~~Services, Services'~~ COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 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 Parts (A)-(B) of this Subparagraph for the third-party laboratory; and
- (2) until onboarding to electronic laboratory reporting is complete, ~~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 telefacsimile, telefacsimile; 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://covid19.nedhhs.gov/media/2889/open>.~~

(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 telefacsimile 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 available at: <https://covid19.nedhhs.gov/media/2889/open>.~~

~~(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 that 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, as applicable, 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, s. 4.10(a)(1);  
Emergency Adoption Eff. September 25, 2020;  
Temporary Adoption Eff. December 1, 2020;*

*Eff. October 1, 2021.*