

1 10A NCAC 41A .0107 is amended with changes as published in 36:23 NCR 1822-1823 as follows:

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3 **10A NCAC 41A .0107 REPORTING OF COVID-19 DIAGNOSTIC TEST RESULTS**

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

- 5 (1) "COVID-19 diagnostic test" means any nucleic acid or antigen test that identifies SARS-CoV-2, the
6 virus that causes COVID-19.
- 7 (2) "Electronic laboratory reporting" means the automated messaging of laboratory reports sent to the
8 Division of Public Health using a machine-readable electronic communication protocol.
- 9 (3) "Healthcare provider" means a healthcare provider as defined in G.S. 130A-476(g)(1).
- 10 (4) "Laboratory" means a facility that performs testing on specimens obtained from humans for the
11 purpose of providing information for health assessment and for the diagnosis, prevention, or
12 treatment of disease and is certified by the United States Department of Health and Human Services
13 under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) at P.L. 100-578 and
14 implementing regulations at 42 C.F.R. 493, which are hereby incorporated by reference, including
15 any subsequent amendments or editions, and available free of charge at
16 <https://www.congress.gov/public-laws/> and <http://ecfr.gov/>, respectively. This definition includes a
17 healthcare provider who performs testing in an on-site facility that meets these requirements.

18 (b) Each person in charge of a laboratory providing diagnostic service in this State shall report the results of ~~all~~
19 COVID-19 diagnostic tests to the Division of Public Health using electronic laboratory reporting. For purposes of
20 COVID-19, a novel coronavirus under Rule .0101(c)(1) of this Section, the required method of reporting set out in
21 Rules .0101(c) and .0102(d)(3) of this Section shall not apply. ~~The report~~ Reports shall be made in **compliance**
22 **alignment** with the requirements for laboratories by entity and type of testing and minimum data elements as set
23 forth in ~~shall include all of the elements required to be reported under~~ the United States Department of Health and
24 Human Services, Services' COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115
25 ~~laboratory data reporting~~ guidance, which is hereby incorporated by reference, including any subsequent amendments
26 and editions, and available free of charge at [https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-](https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf)
27 [reporting-guidance.pdf](https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf).

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

- 29 (1) submits a COVID-19 Laboratory Data Automation Registration form to the Division of Public
30 Health and acts to onboard to electronic laboratory reporting. This form shall be submitted within
31 seven calendar days of the date the laboratory starts performing COVID-19 diagnostic testing and
32 shall contain the following elements:
- 33 (A) the name, address, phone number, and CLIA number of the laboratory;
- 34 (B) the name, address, and phone number of the person in charge of the laboratory or that
35 person's designee;
- 36 (C) the type of test performed, testing capacity, and whether the laboratory will use a third-
37 party laboratory to perform part or all of the testing; and

- 1 (D) if the laboratory will use a third-party laboratory to perform part or all of the testing, the
2 information in Parts (A)-(B) of this Subparagraph for the third-party laboratory; and
- 3 (2) until onboarding to electronic laboratory reporting is ~~complete, ecomplete:~~
- 4 (A) reports the results of positive COVID-19 diagnostic tests to the Division of Public Health,
5 including all elements required in Paragraph (b) of this Rule, by telefacsimile.
6 ~~telefacsimile; and~~
- 7 (B) ~~reports the aggregate number of positive and negative nucleic acid COVID-19 diagnostic~~
8 ~~tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests~~
9 ~~per day to the Division of Public Health through an online survey available at:~~
10 ~~<https://covid19.ncdhhs.gov/media/2889/open>.~~
- 11 (d) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory that completes
12 fewer than 50 total COVID-19 diagnostic tests per week submits results as set out in Subparagraph (c)(2) of this Rule.
- 13 ~~(e) Healthcare providers who order COVID-19 diagnostic testing in this State shall:~~
- 14 (1) ~~report the results of positive COVID-19 diagnostic tests by telefacsimile to the local health director~~
15 ~~in the county or district where the patient resides. The report shall contain:~~
- 16 (A) ~~patient first and last name, date of birth, address, county of residence, phone number, sex,~~
17 ~~race, and ethnicity;~~
- 18 (B) ~~provider name, address, phone number, and NPI;~~
- 19 (C) ~~the specimen collection date, the test order date, and the test result date;~~
- 20 (D) ~~the test result; and~~
- 21 (E) ~~all other available elements required in Paragraph (b) of this Rule; and~~
- 22 (2) ~~report the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and~~
23 ~~the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the~~
24 ~~Division of Public Health through an online survey available at:~~
25 ~~<https://covid19.ncdhhs.gov/media/2889/open>.~~
- 26 ~~(f) The requirements set forth in Paragraph (e) of this Rule shall be considered met if a healthcare provider:~~
- 27 (1) ~~verifies that the laboratory that receives the specimen for testing will report the test result in~~
28 ~~accordance with Paragraph (b) of this Rule; and~~
- 29 (2) ~~includes patient first and last name, date of birth, address, county of residence, phone number, sex,~~
30 ~~race, ethnicity, and specimen collection date on the lab order.~~
- 31 ~~(g) The requirement for healthcare providers to report COVID-19 diagnostic test results, as set out in Paragraph (e)~~
32 ~~of this Rule, is separate from the requirement for physicians to report suspected infections of COVID-19, a novel~~
33 ~~coronavirus, including positive COVID-19 diagnostic test results, in accordance with G.S. 130A-135 and Rules~~
34 ~~.0101(a) and .0102(a) of this Section.~~
- 35 ~~(h)(e)~~ Laboratories and healthcare providers who that are required to report under this Rule shall report positive
36 COVID-19 diagnostic test results immediately upon receiving the result and negative COVID-19 diagnostic test
37 results, as required by Paragraph (b) of this Rule, [applicable,] results within 24 hours of receiving the result. Results

1 ~~reported to a local health department under this Rule shall be forwarded to the Division of Public Health within 24~~
2 ~~hours of receipt by the local health department.~~

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4 *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)~~;*
5 *Emergency Adoption Eff. September 25, 2020;*
6 *Temporary Adoption Eff. December 1, 2020;*
7 *Eff. October 1, 2021; ~~2021~~.*
8 *Amended Eff. October 1, 2022.*