

Fiscal Note for Permanent Amendment of 10A NCAC 41A .0101

Agency:	North Carolina Department of Health and Human Services Division of Public Health, Epidemiology Section Communicable Disease Branch
Rule Citations:	10A NCAC 41A .0101 Reportable Diseases and Conditions
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Rulemaking Authority:	G.S. 130A-134 G.S. 130A-135 G.S. 130A-139 G.S. 130A-141
State Impact:	Yes
Local Impact:	Yes
Private Sector:	Yes
Substantial Impact:	Yes ¹

Introduction and Purpose

This fiscal note analyzes the impact of adding novel coronavirus to the list of reportable diseases and conditions in 10A NCAC 41A .0101. A novel coronavirus is a newly identified, emerging coronavirus. SARS-CoV-2, the virus causing COVID-19, is a type of novel coronavirus. COVID-19 was first identified in December of 2019. It is highly infectious and, since its discovery, has spread worldwide, causing a severe pandemic. Individuals with COVID-19 may be asymptomatic or may experience illness ranging in severity from mild illness to death. COVID-19 is the third novel coronavirus to emerge in the past two decades, preceded by SARS and MERS. Other novel coronaviruses could have the same potential for spread and significant impact.

It is imperative that public health authorities be rapidly notified when novel coronavirus infections and infections causing death are suspected or confirmed so that appropriate control measures can be implemented to prevent further spread. For this reason, in response to the current COVID-19 pandemic, the State Health Director issued two temporary orders, pursuant to G.S. 130A-141.1, effective February 3, 2020 and March 23, 2020 that required reporting of infections and deaths, respectively. On February 5, 2020, the Commission for Public Health adopted an amendment to 10A NCAC 41A .0101 under emergency procedures and simultaneously proposed to amend 10A NCAC 41A .0101 under temporary

¹ "Substantial economic impact" is defined at G.S. 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."

procedures to update the communicable diseases and conditions reporting requirements to include novel coronavirus infections. The emergency amendment went into effect on February 17, 2020. The temporary amendment was subsequently amended to also include novel coronavirus infections causing death, was adopted on March 24, 2020, and became effective April 24, 2020. The Commission for Public Health is now proposing to adopt a permanent amendment to ensure that these reporting requirements do not expire from the Code. Adding reporting requirements for novel coronavirus infections and infections causing death—not just COVID-19—ensures that novel coronaviruses will be reportable as they emerge, thereby aiding public health with conducting early surveillance and deploying a rapid response to outbreaks.

Background

The core mission of the Communicable Disease Branch of the North Carolina Department of Health and Human Services, Division of Public Health, Epidemiology Section is to identify, prevent, and control the spread of communicable diseases. Because communicable diseases can have so much impact on the population, the surveillance and control of such diseases is an important part of protecting the public's health. Public health disease surveillance involves interaction between multiple partners in local government, state government, and the private sector and that partnership is reflected in existing State statutes and rules. Specifically, G.S. 130A, Article 6 requires that physicians and laboratories report confirmed and reasonably suspected cases of the communicable diseases and conditions that have been identified by the Commission for Public Health and enumerated in the rule 10A NCAC 41A .0101.

G.S. 130A-135 requires that a physician submit the report of the communicable disease or condition to the local health department that serves the area in which the physician is consulted. Pursuant to G.S. 130A-140, local health departments are then required to forward those reports to the North Carolina Department of Health and Human Services, Division of Public Health. This information is ultimately housed in the North Carolina Electronic Disease Surveillance System (NC EDSS), to which the Division of Public Health and local health department staff have access. Pursuant to G.S. 130A-139, laboratories are required to submit positive test results for the communicable diseases and conditions listed in 10A NCAC 41A .0101 to the Division of Public Health. Lab results are also retained in NC EDSS and are visible to Division of Public Health and local health department staff.

Requiring the reporting of novel coronaviruses is of critical importance to protecting the public's health. Coronaviruses consist of wide range of viruses that historically infect a diversity of species, including humans. Most known coronaviruses are species-specific; however, there have been certain incidents of cross-species transmission resulting in severe human illness. SARS and MERS are prior examples of this. COVID-19 is the current example of a virus that appears to have jumped from an animal species to humans and is now spreading worldwide via person to person transmission. Mild to severe illness and deaths among infected persons have been observed. By requiring reporting of novel coronaviruses, which includes COVID-19, and by conducting timely surveillance, public health can monitor the intensity of transmission within North Carolina and use this data to inform the implementation of control measures that are essential to reducing further spread of the disease.

Description of Proposed Rules

Technical Amendments

We have made several technical amendments to the rules to correct and clarify existing language. For example, we have changed “spp” to its proper abbreviation of “spp.” in several places; corrected the spelling of the terms “vancomycin” and “cayetanensis,”; and given hantavirus and hemorrhagic fever virus, which are two distinct virus types, their own lines in the list of organisms or organism products that must be reported under the rule. These changes are technical in nature and will not impact how the rule operates. The changes are therefore not expected to result in an economic impact and are not discussed

further in the Impact Analysis section below.

Reporting Requirements for Novel Coronavirus

We have amended the language of this rule to require that known or reasonably suspected novel coronavirus infections causing death be reported within 24 hours; that known or reasonably suspected novel coronavirus infection be reported immediately; and that laboratories report isolation or specific identification of novel coronavirus, human strain, or its products, from human clinical specimens. The time spent by the private sector and local government employees reporting known or reasonably suspected cases of novel coronavirus is expected to be an opportunity cost. State-level staff will also need to review these submitted reports, which will result in an economic impact associated with the cost of staff time. There are also one-time costs that will be incurred by State government and private laboratories related to meeting the information technology needs to handle the volume of incoming reports. These expected economic impacts are discussed in further detail in the following section.

Impact Analysis

Private Sector Impact

Making COVID-19 reportable has an impact on the private sector- specifically, on clinicians consulted by patients who have or may have COVID-19 and on commercial laboratories that conduct COVID-19 testing. The impact on physicians to report their cases consists of time spent by their nursing staff who typically submit the required communicable disease and condition reports on behalf of the diagnosing physician. These reports are submitted to any of the 85 local health departments in North Carolina and should be directed to the local health department that serves the area in which the physician is consulted. These reports consist of important data that is essential to public health surveillance efforts, including getting a larger picture of disease transmission trends and enabling local health department staff to conduct contact tracing. For the private sector, the COVID-19 pandemic, which has resulted in thousands of cases of the disease in North Carolina, along with required reporting, will result in an increased amount of time spent submitting reports to local health departments of known or reasonably suspected cases of COVID-19. We anticipate that for most physicians this will be an opportunity cost, as many physicians will likely not hire additional staff to assist with this reporting work.

Commercial laboratories will similarly see an increase in time spent by laboratory staff to submit COVID-19 test results to the Department of Health and Human Services, Division of Public Health; however, much of laboratory reporting is automated and the requirement that COVID-19 test results be reported to the state are, therefore, not likely to result in an economic impact. Commercial laboratories may experience a one-time economic impact resulting from time that must be spent by IT programmers to modify laboratories' Laboratory Information Systems (LIMS) to facilitate this reporting.

The total costs associated with this work for physicians and for commercial labs are outlined in Table 1 below. The calculations in Table 1 are based on the number of cases that were seen during first six months of the pandemic in North Carolina and are estimated at \$3,139,077. If the pandemic were to settle over the next six months, ongoing cost estimates might be comparable; however, this is difficult to predict as the second six-month period of the pandemic in North Carolina also encompasses the colder months of the year, which could impact disease incidence. As this is a new virus, there is no reference to make realistic projections with certainty.

Local Impact

Required reporting of novel coronavirus will also impact communicable disease nursing staff employed at North Carolina's 85 local health departments. This cohort of specialized staff members spends time reviewing the reports of novel coronavirus that are submitted to the local health departments by physicians and laboratories, entering and expanding case data in the state surveillance database NC

COVID. (See more about NC COVID under the section titled “State Impact”). These staff members also conduct follow up with patients to obtain information that is important for communicable disease surveillance, the implementation of disease control measures, and the provision of appropriate health care services but that may not have been included in the initial reports.

The total cost associated with this work by local public health agencies is outlined in Table 1 below. Based on our expertise and extensive experience working closely with local health department staff, we estimate that it takes a communicable disease nurse at a local health department approximately 30 minutes to review a report of novel coronavirus. Based on the number of cases we have documented in the first six months of the pandemic in North Carolina, we estimate the total cost for the time spent reviewing reports of novel coronavirus to amount to \$2,360,560. Based on our experience, we expect that this may be an opportunity cost, as many local health departments may not hire new staff to assist with this reporting work.

State Impact

The State impact has two components: impacts to the Division of Public Health, Epidemiology Section, Communicable Disease Branch and impacts to the Division of Public Health, State Laboratory of Public Health.

The Epidemiology Section, Communicable Disease Branch operates the NC COVID database. NC COVID is an additional instance of the North Carolina Electronic Disease Surveillance System (NC EDSS), the statewide database for reportable communicable diseases. The need to create a separate database arose from the volume of reported COVID-19 data. While there was no cost for the instance itself, the Surveillance Systems Unit Manager in the Communicable Disease Branch estimates that the three programmers who worked on setting up this additional instance spent approximately 80 hours each on this task. According to the Communicable Disease Branch, the average hourly salary of these program staff is \$57.50.

The information included in the NC COVID reports is reviewed by epidemiologists in the Communicable Disease Branch. Upon conducting a review of each report that is entered into NC COVID, these epidemiologists also provide as-needed follow-up with consultations for reports of cases and deaths related to novel coronavirus.

Due to the large workload created by the high number of positive laboratory tests received by fax (from laboratories that have not developed a capacity to transmit COVID-19 test results to the State electronically), 10 temporary surge staff members were hired at the State level to assist epidemiologists in the Communicable Disease Branch in reviewing the reports submitted to NC COVID. In addition to this cohort of temporary staff who assist with reviewing the reports submitted to NC COVID, three temporary staff were hired to further assist the Communicable Disease Branch with program coordination and analytic work related to receiving COVID-19 reports. According to figures provided by the Communicable Disease Branch, these 13 staff members are estimated to earn an average hourly wage of approximately \$24.00 per hour and all work full-time. Hiring for these temporary positions began in June 2020; however, for the purpose of using past data from February to August 2020 to make projections for future costs and for consistency and ease of comparison, we have presented the cost of hiring these temporary staff for a six-month period in Table 1 below.

The State Laboratory of Public Health at the Division of Public Health serves as the main clinical laboratory for local health departments and has conducted a significant portion of the COVID-19 testing that has been done in North Carolina since the pandemic’s arrival. In addition to testing these specimens and reporting the results to submitting providers at the local health departments, the State Laboratory of Public Health- like commercial laboratories- also needed to program its LIMS to enable the electronic

reporting of COVID-19 test results into NC EDSS.

The total cost associated with this work at the State level is \$1,145,749.

Overall Impact

The total costs associated with this work is outlined in Table 1 below. Based on the number of cases documented in North Carolina during the first six months of the pandemic, those costs are estimated to amount to \$6,645,386. While this figure could be used to estimate an annual cost, the workload related to novel coronavirus reporting in the future will be determined by rates of transmission, characteristics of COVID-19 that may not yet be known to us, and other factors, which collectively make an estimate challenging to calculate at this time.

Table 1: The Total Estimated Impact

Table 1 shows the total estimated economic impact of this rule change. Figures are based on the total of approximately 152,000 reports involving novel coronavirus in North Carolina from February through August 21, 2020. For this analysis, it was assumed that all reports were made both by a physician and a laboratory. It is difficult to predict future trends of COVID-19. The fiscal impact on local government was calculated using the mean hourly wage for a Public Health Nurse II, which was provided by the Public Health Nursing Program in the North Carolina Division of Public Health. The fiscal impact on State government was calculated using the mean hourly wage for an epidemiologist. The fiscal impact on the private sector was calculated using the amount of time estimated for physician office staff (usually a registered nurse) to fax medical information to the local health department and/or answer medical questions from the local health department. The wage for this position was obtained from the 2020 State Occupational Employment and Wage Estimates in NC published by the Bureau of Labor Statistics for Registered Nurses. At the State Laboratory of Public Health, the one-time cost of IT programming to add SARS-CoV-2 to electronically reported results is estimated based on 80 hours of work required by Application System Analysts II, whose hourly compensation of \$43.53 The same cost base was applied to estimate cost at private commercial laboratories.

Table 1

A. Impact on Private Sector, Feb-Aug 2020			
# Events Reported	Total Hours Spent by Registered Nurse to Report One (1) Event	Hourly Salary of Private Sector Registered Nurse ²	Total Cost
152,000	0.33	\$59.11	\$2,964,957
Over 300 Reporting Laboratories (grouped by hospital networks in 50 reporting entities)	Total Hours Spent by an IT Programmer to Update a Reporting Entity's LIMS to Enable Reporting	Hourly Salary of IT Programmer²	Total Cost
50	80	\$43.53	\$174,120
Total Cost to Private Sector, Feb-Aug 2020			\$3,139,077

² Sources for salary data and compensation: Bureau of Labor Statistics Employer Costs for Employee Compensation news release, March 2020 <https://www.bls.gov/news.release/pdf/ecec.pdf> and https://www.bls.gov/oes/current/oes_nc.htm#29-0000.

B. Impact on Local Government, Feb-Aug 2020			
# Events Reported	Total Hours Spent by Registered Nurse to Report One (1) Event	Hourly Salary of Registered Nurse at Local Health Dept.	Total Cost
152,000	.5	\$31.06	\$2,360,560
Total Cost to Local Government, Feb-Aug 2020			\$2,360,560
C. Impact on State Government: Division of Public Health, Epidemiology Section, Communicable Disease Branch, and State Laboratory of Public Health, Feb-Aug 2020			
# Events Reported	Total Hours per Event Reported	Hourly Salary of Epidemiologist²	Total Cost
152,000	.17	\$32.08	\$828,947
# IT Programmer Staff to Set Up NC COVID Database	Total Hours Spent by Each IT Programmer	Hourly Salary of State IT Programmer	Total Cost
3	80	\$57.50	\$13,800
# Temporary Staff for Communicable Disease Branch	Total Hours per Staff Member per Week	Average Estimated Hourly Salary	Total Cost
13	40	\$24.00	\$299,520 ³
Number of State Laboratory of Public Health LIMS	Total Hours Spent by an IT Programmer to Update the State Laboratory's LIMS to Enable Reporting	Hourly Salary of IT Programmer	Total Cost
1	80	\$43.53	\$3,482
Total Cost to State Government, Feb-Aug 2020			\$1,145,749
TOTAL ECONOMIC IMPACT, FEB-AUG 2020			\$6,645,386

Summary

The amendment of 10A NCAC 41A .0101 will aid the State in more accurately 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 table below summarizes the estimated costs to public and private entities during the first six months of the pandemic, including one-time IT system investments plus staff time opportunity costs that will be

³ As noted in the section titled "State Impact," for the purpose of using past data from February to August 2020 (as is done elsewhere in our calculations) to make projections for future costs and for consistency and ease of comparison, the value shown here represents the costs to State government across a six-month time period. It should be noted, though, that because hiring for these temporary positions did not begin until June 2020 the actual cost to State government between February and August 2020 was likely much lower.

ongoing. Estimated staff time costs for nurses and epidemiologists exceeded six million dollars from February through August. The COVID-19 pandemic presents an unprecedented public health crisis and future costs and benefits of the proposed reporting requirements impacting the State, local government, and the private sector are difficult to predict as they will depend on virus transmission trends.

Table 2

All Costs, Feb-Aug 2020 (One-Time v. Ongoing Costs)				
	One-Time IT Programming Costs	One-Time Surge Staff Costs	Ongoing Staffing Costs	Total Costs
Private Sector Nursing Staff	--	--	\$2,964,957	\$2,964,957
Private Sector Laboratories	\$174,120	--	--	\$174,120
Local Health Departments	--	--	\$2,360,560	\$2,360,560
State Government	\$17,282	\$299,520	\$828,947	\$1,145,749
Total	\$191,402	\$299,520	\$6,154,464	\$6,645,386

Alternatives

Pursuant to G.S. 150B-21.4(b2)(5), when an agency concludes its analysis and determines that the proposed rules will have a substantial economic impact, 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.

One alternative would be for North Carolina to rely on data collected in other jurisdictions, such as neighboring states and states with demography that is comparable to North Carolina. This alternative was not pursued, however, because it would not provide the detailed, specific information that North Carolina needs to inform its COVID-19 response. The pandemic does not affect communities uniformly and many characteristics, such as demographics, environment, residents’ occupations, interactions within the community, access to health care, cultural norms, control measures and policies already implemented, and more can affect the spread of COVID-19 and the approaches needed to control the pandemic. While looking to similar jurisdictions can provide some insights useful to North Carolina’s pandemic response, this approach would not provide the level of detailed, timely, and accurate information that is critical to informing the State’s COVID-19 pandemic response.

Another alternative would be to collect data at a lower frequency by requiring that physicians report COVID-19 cases and deaths and that laboratories report COVID-19 test results less often. This approach, however, would likely have the consequence of limiting the State’s ability to implement timely, effective control measures and to interrupt the chains of transmission of COVID-19.

1 10A NCAC 41A .0101 is proposed for amendment as follows:
2

3 **10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS**

4 (a) The following named diseases and conditions are declared to be dangerous to the public health and are
5 hereby made reportable within the time period specified after the disease or condition is reasonably
6 suspected to exist:

- 7 (1) acquired immune deficiency syndrome (AIDS) - 24 hours;
- 8 (2) acute flaccid myelitis – 7 days;
- 9 (3) anaplasmosis – 7 days;
- 10 (4) anthrax - immediately;
- 11 (5) arboviral infection, neuroinvasive – 7 days;
- 12 (6) babesiosis – 7 days;
- 13 (7) botulism - immediately;
- 14 (8) brucellosis - 7 days;
- 15 (9) campylobacter infection - 24 hours;
- 16 (10) *Candida auris* - 24 hours;
- 17 (11) Carbapenem-Resistant Enterobacteriaceae (CRE) – 24 hours;
- 18 (12) chancroid - 24 hours;
- 19 (13) chikungunya virus infection - 24 hours;
- 20 (14) chlamydial infection (laboratory confirmed) - 7 days;
- 21 (15) cholera - 24 hours;
- 22 (16) Creutzfeldt-Jakob disease – 7 days;
- 23 (17) cryptosporidiosis – 24 hours;
- 24 (18) cyclosporiasis – 24 hours;
- 25 (19) dengue - 7 days;
- 26 (20) diphtheria - 24 hours;
- 27 (21) *Escherichia coli*, shiga toxin-producing infection - 24 hours;
- 28 (22) ehrlichiosis – 7 days;
- 29 (23) foodborne disease, including *Clostridium perfringens*, staphylococcal, *Bacillus cereus*, and
30 other and unknown causes - 24 hours;
- 31 (24) gonorrhea - 24 hours;
- 32 (25) granuloma inguinale - 24 hours;
- 33 (26) *Haemophilus influenzae*, invasive disease - 24 hours;
- 34 (27) Hantavirus infection – 7 days;
- 35 (28) Hemolytic-uremic syndrome – 24 hours;
- 36 (29) Hemorrhagic fever virus infection – immediately;
- 37 (30) hepatitis A - 24 hours;
- 38 (31) hepatitis B - 24 hours;
- 39 (32) hepatitis B carriage - 7 days;
- 40 (33) hepatitis C, acute – 7 days;
- 41 (34) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
- 42 (35) influenza virus infection causing death – 24 hours;
- 43 (36) legionellosis - 7 days;
- 44 (37) leprosy – 7 days;
- 45 (38) leptospirosis - 7 days;
- 46 (39) listeriosis – 24 hours;
- 47 (40) Lyme disease - 7 days;
- 48 (41) Lymphogranuloma venereum - 7 days;

- 1 (42) malaria - 7 days;
2 (43) measles (rubeola) - immediately;
3 (44) meningitis, pneumococcal - 7 days;
4 (45) meningococcal disease - 24 hours;
5 (46) Middle East respiratory syndrome (MERS) - 24 hours;
6 (47) monkeypox - 24 hours;
7 (48) mumps - 7 days;
8 (49) nongonococcal urethritis - 7 days;
9 (50) novel coronavirus infection causing death - 24 hours;
10 (51) novel coronavirus infection - immediately;
11 ~~(50)~~(52) novel influenza virus infection - immediately;
12 ~~(51)~~(53) plague - immediately;
13 ~~(52)~~(54) paralytic poliomyelitis - 24 hours;
14 ~~(53)~~(55) pelvic inflammatory disease - 7 days;
15 ~~(54)~~(56) psittacosis - 7 days;
16 ~~(55)~~(57) Q fever - 7 days;
17 ~~(56)~~(58) rabies, human - 24 hours;
18 ~~(57)~~(59) rubella - 24 hours;
19 ~~(58)~~(60) rubella congenital syndrome - 7 days;
20 ~~(59)~~(61) salmonellosis - 24 hours;
21 ~~(60)~~(62) severe acute respiratory syndrome (SARS) - 24 hours;
22 ~~(61)~~(63) shigellosis - 24 hours;
23 ~~(62)~~(64) smallpox - immediately;
24 ~~(63)~~(65) spotted fever rickettsiosis - 7 days;
25 ~~(64)~~(66) Staphylococcus aureus with reduced susceptibility to vancomycin - 24 hours;
26 ~~(65)~~(67) streptococcal infection, Group A, invasive disease - 7 days;
27 ~~(66)~~(68) syphilis - 24 hours;
28 ~~(67)~~(69) tetanus - 7 days;
29 ~~(68)~~(70) toxic shock syndrome - 7 days;
30 ~~(69)~~(71) trichinosis - 7 days;
31 ~~(70)~~(72) tuberculosis - 24 hours;
32 ~~(71)~~(73) tularemia - immediately;
33 ~~(72)~~(74) typhoid - 24 hours;
34 ~~(73)~~(75) typhoid carriage (Salmonella typhi) - 7 days;
35 ~~(74)~~(76) typhus, epidemic (louse-borne) - 7 days;
36 ~~(75)~~(77) vaccinia - 24 hours;
37 ~~(76)~~(78) varicella - 24 hours;
38 ~~(77)~~(79) vibrio infection (other than cholera) - 24 hours;
39 ~~(78)~~(80) whooping cough - 24 hours;
40 ~~(79)~~(81) yellow fever - 7 days; and
41 ~~(80)~~(82) zika virus - 24 hours.

42 (b) For purposes of reporting, "confirmed human immunodeficiency virus (HIV) infection" is defined as a
43 positive virus culture, repeatedly reactive EIA antibody test confirmed by western blot or indirect
44 immunofluorescent antibody test, positive nucleic acid detection (NAT) test, or other confirmed testing
45 method approved by the Director of the State Public Health Laboratory conducted on or after February 1,
46 1990. In selecting additional tests for approval, the Director of the State Public Health Laboratory shall
47 consider whether such tests have been approved by the federal Food and Drug Administration,

1 recommended by the federal Centers for Disease Control and Prevention, and endorsed by the Association
2 of Public Health Laboratories.

3 (c) In addition to the laboratory reports for Mycobacterium tuberculosis, Neisseria gonorrhoeae, and
4 syphilis specified in G.S. 130A-139, laboratories shall report using electronic laboratory reporting (ELR),
5 secure telecommunication, or paper reports.

6 (1) Isolation or other specific identification of the following organisms or their products from
7 human clinical specimens:

8 (A) ~~Anaplasma spp., spp.,~~ the causes of anaplasmosis.

9 (B) Any ~~hantavirus, hantavirus, or hemorrhagic fever virus.~~

10 (C) Any hemorrhagic fever virus.

11 ~~(C)(D)~~ Arthropod-borne virus (any type).

12 ~~(D)(E)~~ Babesia spp., the cause of babesiosis.

13 ~~(E)(F)~~ Bacillus anthracis, the cause of anthrax.

14 ~~(F)(G)~~ Bordetella pertussis, the cause of whooping cough (pertussis).

15 ~~(G)(H)~~ Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).

16 ~~(H)(I)~~ Brucella spp., the causes of brucellosis.

17 ~~(I)(J)~~ Campylobacter spp., the causes of campylobacteriosis.

18 ~~(J)(K)~~ Candida auris.

19 ~~(K)(L)~~ Carbapenem-Resistant Enterobacteriaceae (CRE).

20 ~~(L)(M)~~ Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis
21 (adult and newborn) and pneumonia of newborns.

22 ~~(M)(N)~~ Clostridium botulinum, a cause of botulism.

23 ~~(N)(O)~~ Clostridium tetani, the cause of tetanus.

24 (P) Coronavirus, novel human strain.

25 ~~(O)(Q)~~ Corynebacterium diphtheriae, the cause of diphtheria.

26 ~~(P)(R)~~ Coxiella burnetii, the cause of Q fever.

27 ~~(Q)(S)~~ Cryptosporidium spp., the cause of human cryptosporidiosis.

28 ~~(R)(T)~~ Cyclospora ~~cayentanensis, cayentanensis,~~ the cause of cyclosporiasis.

29 ~~(S)(U)~~ Dengue virus.

30 ~~(T)(V)~~ Ehrlichia spp., the causes of ehrlichiosis.

31 ~~(U)(W)~~ Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic
32 uremic syndrome, and thrombotic thrombocytopenic purpura.

33 ~~(V)(X)~~ Francisella tularensis, the cause of tularemia.

34 ~~(W)(Y)~~ Hepatitis A virus.

35 ~~(X)(Z)~~ Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.

36 ~~(Y)(AA)~~ Human Immunodeficiency Virus, the cause of AIDS.

37 ~~(Z)(BB)~~ Legionella spp., the causes of legionellosis.

38 ~~(AA)(CC)~~ Leptospira spp., the causes of leptospirosis.

39 ~~(BB)(DD)~~ Listeria monocytogenes, the cause of listeriosis.

40 ~~(CC)(EE)~~ Measles virus.

41 ~~(DD)(FF)~~ Middle East respiratory syndrome virus.

42 ~~(EE)(GG)~~ Monkeypox.

43 ~~(FF)(HH)~~ Mumps virus.

44 ~~(GG)(II)~~ Mycobacterium leprae, the cause of leprosy.

45 ~~(HH)(JJ)~~ Plasmodium falciparum, P. malariae, P. ovale, and P. vivax, the causes of
46 malaria in humans.

47 ~~(II)(KK)~~ Poliovirus (any), the cause of poliomyelitis.

48 ~~(JJ)(LL)~~ Rabies virus.

49 ~~(KK)(MM)~~ Rickettsia spp., the cause of spotted fever rickettsiosis.

50 ~~(LL)(NN)~~ Rubella virus.

51 ~~(MM)(OO)~~ Salmonella spp., the causes of salmonellosis.

- 1 ~~(NN)~~(PP) Shigella spp., the causes of shigellosis.
2 ~~(OO)~~(QQ) Smallpox virus, the cause of smallpox.
3 ~~(PP)~~(RR) Staphylococcus aureus with reduced susceptibility to ~~vanomycin~~vancomycin.
4 ~~(QQ)~~(SS) Trichinella spiralis, the cause of trichinosis.
5 ~~(RR)~~(TT) Vaccinia virus.
6 ~~(SS)~~(UU) Varicella virus.
7 ~~(TT)~~(VV) Vibrio spp., the causes of cholera and other vibrioses.
8 ~~(UU)~~(WW) Yellow fever virus.
9 ~~(VV)~~(XX) Yersinia pestis, the cause of plague.
10 ~~(WW)~~(YY) Zika virus.
- 11 (2) Isolation or other specific identification of the following organisms from normally sterile
12 human body sites:
13 (A) Group A Streptococcus pyogenes (group A streptococci).
14 (B) Haemophilus influenzae, serotype b.
15 (C) Neisseria meningitidis, the cause of meningococcal disease.
- 16 (3) Positive serologic test results, as specified, for the following infections:
17 (A) Fourfold or greater changes or equivalent changes in serum antibody titers to:
18 (i) Any arthropod-borne virus associated with neuroinvasive disease.
19 (ii) Anaplasma spp., the cause of anaplasmosis.
20 (iii) Any hantavirus or hemorrhagic fever virus.
21 (iv) Chlamydia psittaci, the cause of psittacosis.
22 (v) Chikungunya virus.
23 (vi) Coxiella burnetii, the cause of Q fever.
24 (vii) Dengue virus.
25 (viii) Ehrlichia spp., the causes of ehrlichiosis.
26 (ix) Measles (rubeola) virus.
27 (x) Mumps virus.
28 (xi) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
29 (xii) Rubella virus.
30 (xiii) Varicella virus.
31 (xiv) Yellow fever virus.
- 32 (B) The presence of IgM serum antibodies to:
33 (i) Any arthropod-borne virus associated with neuroinvasive disease.
34 (ii) Chikungunya virus.
35 (iii) Chlamydia psittaci.
36 (iv) Dengue virus.
37 (v) Hepatitis A virus.
38 (vi) Hepatitis B virus core antigen.
39 (vii) Mumps virus.
40 (viii) Rubella virus.
41 (ix) Rubeola (measles) virus.
42 (x) Yellow fever virus.
- 43 (4) Laboratory results from tests to determine the absolute and relative counts for the T-helper
44 (CD4) subset of lymphocytes and all results from tests to determine HIV viral load.
- 45 (5) Identification of CRE from a clinical specimen associated with either infection or
46 colonization, including all susceptibility results and all phenotypic or molecular test results.
- 47 (d) Laboratories utilizing electronic laboratory reporting (ELR) shall report in addition to those listed under
48 Paragraph (c) of this Rule:
49 (1) All positive laboratory results from tests used to diagnosis chronic Hepatitis C Infection,
50 including the following:

- 1 (A) Hepatitis C virus antibody tests (including the test specific signal to cut-off (s/c)
2 ratio);
3 (B) Hepatitis C nucleic acid tests;
4 (C) Hepatitis C antigen(s) tests; and
5 (D) Hepatitis C genotypic tests.
6 (2) All HIV genotypic test results, including when available:
7 (A) The entire nucleotide sequence; or
8 (B) The pol region sequence (including all regions: protease (PR)/reverse transcriptase
9 (RT) and integrase (INI) genes, if available).
10 (3) All test results for Interferon Gamma Release Assays.
11 (e) For the purposes of reporting, Carbapenem-Resistant Enterobacteriaceae (CRE) are defined as:
12 (1) Enterobacter ~~spp,spp.~~, E.coli or Klebsiella spp positive for a known carbapenemase
13 resistance mechanism or positive on a phenotypic test for carbapenemase production; or
14 (2) Enterobacter ~~spp,spp.~~, E.coli or Klebsiella spp resistant to any carbapenem in the absence
15 of carbapenemase resistance mechanism testing or phenotypic testing for carbapenemase
16 production.
17

18 *History Note: Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141;*
19 *Amended Eff. October 1, 1994; February 1, 1990;*
20 *Temporary Amendment Eff. July 1, 1997;*
21 *Amended Eff. August 1, 1998;*
22 *Temporary Amendment Eff. February 13, 2003; October 1, 2002; February 18, 2002; June*
23 *1, 2001;*
24 *Amended Eff. April 1, 2003;*
25 *Temporary Amendment Eff. November 1, 2003; May 16, 2003;*
26 *Amended Eff. January 1, 2005; April 1, 2004;*
27 *Temporary Amendment Eff. June 1, 2006;*
28 *Amended Eff. April 1, 2008; November 1, 2007; October 1, 2006;*
29 *Temporary Amendment Eff. January 1, 2010;*
30 *Temporary Amendment Expired September 11, 2011;*
31 *Amended Eff. July 1, 2013;*
32 *Temporary Amendment Eff. December 2, 2014;*
33 *Amended Eff. October 1, 2015;*
34 *Emergency Amendment Eff. March 1, 2016;*
35 *Temporary Amendment Eff. July 1, 2016;*
36 *Amended Eff. January 1, 2018; October 1, 2016;*
37 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff.*
38 *January 9, 2018;*
39 *Amended Eff. October 1, 2018;*
40 *Emergency Amendment Eff. February 17, 2020;*
41 *Temporary Amendment Eff. April 24, 2020;*
42 *Amended Eff. July 1, 2020.*