

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0101

**DEADLINE FOR RECEIPT: Friday, September 7, 2018**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

*On the Submission for Permanent Rule Form, Box 8, you state that local funds are affected; however, the Notice of Text said they were not. Please review and revise if necessary.*

*In (a)(6), line 17, please remove the extra closing parenthesis after "(6)" As you published it correctly, you do not need to show it as a change – simply delete it.*

*Also on line 17, please underline "24 hours;" as this is new language.*

*In (c), Page 3, line 27, I take it your regulated public knows what the ELR is and how to use it?*

*Please delete the blank line space on line 29.*

*In (c)(5), Page 5, line 31, since you do not define the term and explain the acronym until Paragraph (e), consider stating what "CRE" stands for here.*

*Please delete the blank line space on line 33.*

*In (d), line 34, should this mirror the language in (c), line 27 and read "electronic laboratory testing (ELR) secure telecommunication"?*

*On line 35, please capitalize "Rule" Since you published this correctly in the Register, you do not have to show this as a change – simply do it.*

*On Page 6, this is not the correct History Note for this Rule. Please replace what you have with the correct History Note from the Code.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder  
Commission Counsel  
Date submitted to agency: August 23, 2018



1           ~~(22)~~(24) Hantavirus infection – 7 days;  
2           ~~(23)~~(25) Hemolytic-uremic syndrome – 24 hours;  
3           ~~(24)~~(26) Hemorrhagic fever virus infection – immediately;  
4           ~~(25)~~(27) hepatitis A - 24 hours;  
5           ~~(26)~~(28) hepatitis B - 24 hours;  
6           ~~(27)~~(29) hepatitis B carriage - 7 days;  
7           ~~(28)~~(30) hepatitis C, acute – 7 days;  
8           ~~(29)~~(31) human immunodeficiency virus (HIV) infection confirmed - 24 hours;  
9           ~~(30)~~(32) influenza virus infection causing death – 24 hours;  
10          ~~(31)~~(33) legionellosis - 7 days;  
11          ~~(32)~~(34) leprosy – 7 days;  
12          ~~(33)~~(35) leptospirosis - 7 days;  
13          ~~(34)~~(36) listeriosis – 24 hours;  
14          ~~(35)~~(37) Lyme disease - 7 days;  
15          ~~(36)~~(38) Lymphogranuloma venereum - 7 days;  
16          ~~(37)~~(39) malaria - 7 days;  
17          ~~(38)~~(40) measles (rubeola) - 24 hours;  
18          ~~(39)~~(41) meningitis, pneumococcal - 7 days;  
19          ~~(40)~~(42) meningococcal disease - 24 hours;  
20          ~~(41)~~(43) Middle East respiratory syndrome (MERS) - 24 hours;  
21          ~~(42)~~(44) monkeypox – 24 hours;  
22          ~~(43)~~(45) mumps - 7 days;  
23          ~~(44)~~(46) nongonococcal urethritis - 7 days;  
24          ~~(45)~~(47) novel influenza virus infection – immediately;  
25          ~~(46)~~(48) plague - immediately;  
26          ~~(47)~~(49) paralytic poliomyelitis - 24 hours;  
27          ~~(48)~~(50) pelvic inflammatory disease – 7 days;  
28          ~~(49)~~(51) psittacosis - 7 days;  
29          ~~(50)~~(52) Q fever - 7 days;  
30          ~~(51)~~(53) rabies, human - 24 hours;  
31          ~~(52)~~(54) Rocky Mountain spotted fever - 7 days;  
32          ~~(53)~~(55) rubella - 24 hours;  
33          ~~(54)~~(56) rubella congenital syndrome - 7 days;  
34          ~~(55)~~(57) salmonellosis - 24 hours;

1 (56)(58) severe acute respiratory syndrome (SARS) – 24 hours;  
2 (57)(59) shigellosis - 24 hours;  
3 (58)(60) smallpox - immediately;  
4 (59)(61) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;  
5 (60)(62) streptococcal infection, Group A, invasive disease - 7 days;  
6 (61)(63) syphilis - 24 hours;  
7 (62)(64) tetanus - 7 days;  
8 (63)(65) toxic shock syndrome - 7 days;  
9 (64)(66) trichinosis - 7 days;  
10 (65)(67) tuberculosis - 24 hours;  
11 (66)(68) tularemia – immediately;  
12 (67)(69) typhoid - 24 hours;  
13 (68)(70) typhoid carriage (Salmonella typhi) - 7 days;  
14 (69)(71) typhus, epidemic (louse-borne) - 7 days;  
15 (70)(72) vaccinia – 24 hours;  
16 (71)(73) vibrio infection (other than cholera) – 24 hours;  
17 (72)(74) whooping cough – 24 hours; and  
18 (73)(75) yellow fever - 7 days.

19 (b) For purposes of reporting, "confirmed human immunodeficiency virus (HIV) infection" is defined as a positive  
20 virus culture, repeatedly reactive EIA antibody test confirmed by western blot or indirect immunofluorescent antibody  
21 test, positive nucleic acid detection (NAT) test, or other confirmed testing method approved by the Director of the  
22 State Public Health Laboratory conducted on or after February 1, 1990. In selecting additional tests for approval, the  
23 Director of the State Public Health Laboratory shall consider whether such tests have been approved by the federal  
24 Food and Drug Administration, recommended by the federal Centers for Disease Control and Prevention, and  
25 endorsed by the Association of Public Health Laboratories.

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

- 29
- 30 (1) Isolation or other specific identification of the following organisms or their products from human  
31 clinical specimens:
- 32 (A) Any hantavirus or hemorrhagic fever virus.
  - 33 (B) Arthropod-borne virus (any type).
  - 34 (C) Bacillus anthracis, the cause of anthrax.
  - 35 (D) Bordetella pertussis, the cause of whooping cough (pertussis).
  - 36 (E) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).

- 1 (F) *Brucella* spp., the causes of brucellosis.
- 2 (G) *Campylobacter* spp., the causes of campylobacteriosis.
- 3 (H) *Candida auris*.
- 4 (I) Carbapenem-Resistant Enterobacteriaceae (CRE).
- 5 ~~(H)~~(J) *Chlamydia trachomatis*, the cause of genital chlamydial infection, conjunctivitis (adult and  
6 newborn) and pneumonia of newborns.
- 7 ~~(H)~~(K) *Clostridium botulinum*, a cause of botulism.
- 8 ~~(H)~~(L) *Clostridium tetani*, the cause of tetanus.
- 9 ~~(K)~~(M) *Corynebacterium diphtheriae*, the cause of diphtheria.
- 10 ~~(L)~~(N) *Coxiella burnetii*, the cause of Q fever.
- 11 ~~(M)~~(O) *Cryptosporidium parvum*, the cause of human cryptosporidiosis.
- 12 ~~(N)~~(P) *Cyclospora cayentanesis*, the cause of cyclosporiasis.
- 13 ~~(O)~~(Q) *Ehrlichia* spp., the causes of ehrlichiosis.
- 14 ~~(P)~~(R) Shiga toxin-producing *Escherichia coli*, a cause of hemorrhagic colitis, hemolytic uremic  
15 syndrome, and thrombotic thrombocytopenic purpura.
- 16 ~~(Q)~~(S) *Francisella tularensis*, the cause of tularemia.
- 17 ~~(R)~~(T) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
- 18 ~~(S)~~(U) Human Immunodeficiency Virus, the cause of AIDS.
- 19 ~~(T)~~(V) *Legionella* spp., the causes of legionellosis.
- 20 ~~(U)~~(W) *Leptospira* spp., the causes of leptospirosis.
- 21 ~~(V)~~(X) *Listeria monocytogenes*, the cause of listeriosis.
- 22 ~~(W)~~(Y) Middle East respiratory syndrome virus.
- 23 ~~(X)~~(Z) Monkeypox.
- 24 ~~(Y)~~(AA) *Mycobacterium leprae*, the cause of leprosy.
- 25 ~~(Z)~~(BB) *Plasmodium falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*, the causes of malaria in  
26 humans.
- 27 ~~(AA)~~(CC) Poliovirus (any), the cause of poliomyelitis.
- 28 ~~(BB)~~(DD) Rabies virus.
- 29 ~~(CC)~~(EE) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
- 30 ~~(DD)~~(FF) Rubella virus.
- 31 ~~(EE)~~(GG) *Salmonella* spp., the causes of salmonellosis.
- 32 ~~(FF)~~(HH) *Shigella* spp., the causes of shigellosis.
- 33 ~~(GG)~~(II) Smallpox virus, the cause of smallpox.
- 34 ~~(HH)~~(JJ) *Staphylococcus aureus* with reduced susceptibility to vanomycin.
- 35 ~~(II)~~(KK) *Trichinella spiralis*, the cause of trichinosis.
- 36 ~~(JJ)~~(LL) Vaccinia virus.
- 37 ~~(KK)~~(MM) *Vibrio* spp., the causes of cholera and other vibrioses.

- 1                   ~~(LL)~~(NN)           Yellow fever virus.
- 2                   ~~(MM)~~(OO)           Yersinia pestis, the cause of plague.
- 3           (2)       Isolation or other specific identification of the following organisms from normally sterile human
- 4           body sites:
- 5           (A)       Group A Streptococcus pyogenes (group A streptococci).
- 6           (B)       Haemophilus influenzae, serotype b.
- 7           (C)       Neisseria meningitidis, the cause of meningococcal disease.
- 8           (3)       Positive serologic test results, as specified, for the following infections:
- 9           (A)       Fourfold or greater changes or equivalent changes in serum antibody titers to:
- 10           (i)       Any arthropod-borne viruses associated with meningitis or encephalitis in a
- 11           human.
- 12           (ii)       Any hantavirus or hemorrhagic fever virus.
- 13           (iii)       Chlamydia psittaci, the cause of psittacosis.
- 14           (iv)       Coxiella burnetii, the cause of Q fever.
- 15           (v)       Dengue virus.
- 16           (vi)       Ehrlichia spp., the causes of ehrlichiosis.
- 17           (vii)       Measles (rubeola) virus.
- 18           (viii)       Mumps virus.
- 19           (ix)       Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
- 20           (x)       Rubella virus.
- 21           (xi)       Yellow fever virus.
- 22           (B)       The presence of IgM serum antibodies to:
- 23           (i) Chlamydia psittaci.
- 24           (ii) Hepatitis A virus.
- 25           (iii) Hepatitis B virus core antigen.
- 26           (iv) Rubella virus.
- 27           (v) Rubeola (measles) virus.
- 28           (vi) Yellow fever virus.
- 29           (4)       Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4)
- 30           subset of lymphocytes and all results from tests to determine HIV viral load.
- 31           (5)       Identification of CRE from a clinical specimen associated with either infection or colonization,
- 32           including all susceptibility results and all phenotypic or molecular test results.
- 33
- 34           (d) Laboratories utilizing electronic laboratory reporting (ELR) shall ~~report~~report in addition to those listed under
- 35           (c) of this rule:
- 36           (1)       All positive laboratory results from tests used to diagnosis chronic Hepatitis C Infection, including
- 37           the following:

- 1 (A) Hepatitis C virus antibody tests (including the test specific signal to cut-off (s/c) ratio);
- 2 (B) Hepatitis C nucleic acid tests;
- 3 (C) Hepatitis C antigen(s) tests; and
- 4 (D) Hepatitis C genotypic tests.
- 5 (2) All HIV genotypic test results, including when available:
- 6 (A) The entire nucleotide sequence; ~~and~~ or
- 7 (B) The pol region sequence (including all regions: protease (PR)/reverse transcriptase (RT)
- 8 and integrase (INI) genes, if available).

9 (e)–For the purposes of reporting, Carbapenem-Resistant Enterobacteriaceae (CRE) are defined as:

- 10 (1) *Enterobacter* spp, *E.coli* or *Klebsiella* spp positive for a known carbapenemase resistance
- 11 mechanism or positive on a phenotypic test for carbapenemase production; or
- 12 (2) *Enterobacter* spp, *E.coli* or *Klebsiella* spp resistant to any carbapenem in the absence of
- 13 carbapenemase resistance mechanism testing or phenotypic testing for carbapenemase production.

14  
15 *Authority G.S. 130A-149;*

16 *Temporary Adoption Eff. January 10, 2002;*

17 *Eff. April 1, 2003;*

18 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*

19 *~~2018-2018;~~*

20 *Eff. October 1, 2018.*

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