Fiscal Note for Permanent Rule Changes for North Carolina Division of Public Health Requires OSBM Review

Agency: NC Commission for Public Health
Dept. Of Health and Human Services, Division of Public Health,
Epidemiology Section, Communicable Disease Branch

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Rule Citations:
10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS (Amendment)

Purpose of Rule Changes: *10A NCAC 41A .0101 - Reportable Diseases and Conditions*
Add Acute Flaccid Myelitis, Babesiosis, Varicella and Interferon Gamma Release Assay testing to Reportable Diseases and Conditions; Re-list Zika in Reportable Diseases and Conditions; Make numerous technical changes related to nomenclature, timing of reporting, and scientific progress in laboratory testing

For proposed rule text, please see Appendix A.

Relevant Statutes: GS 130A-134; 130A-135; 130A-139; 130A-141

State Impact: Yes (minimal opportunity costs)
Local Impact: Yes (minimal opportunity costs)
Substantial Economic Impact: No

Reason for Proposed Amendments:
Acute flaccid myelitis (AFM) is a syndrome characterized by rapid onset of flaccid weakness in one or more limbs and distinct abnormalities of the spinal cord gray matter on magnetic resonance imaging (MRI). Surveillance data are critical for better characterizing the clinical features, epidemiology, and outcomes of cases of AFM; facilitating interpretation of apparent increases in AFM; and better defining the etiologic agent(s) in order to focus prevention efforts.

Varicella (chickenpox) is a febrile illness characterized by a distinctive pruritic rash that progresses rapidly from macules to papules to vesicular lesions. Varicella is caused by primary infection with varicella zoster virus. Varicella is highly communicable and is spread person to person through respiratory tract secretions or contact with vesicular fluid from skin lesions. Rapid case identification is critical for the initiation of public health action and outbreak control, especially in the setting of cases in childcare centers, schools, and other group settings. Surveillance of disease is important to understanding the incidence of varicella in the post-vaccine era and appropriately responding to cases and outbreaks.

Babesiosis is a parasitic disease cause by an infection with protozoa of the Babesia genus (Babesia microti and other species). Most infections are probably asymptomatic; however, some infections are characterized by fever, chills, sweating, myalgias, fatigue, hepatosplenomegaly, and hemolytic anemia. Transfusion—transmitted babesiosis is the most frequently reported parasitic disease associated with transfusions in the United States. While tickborne transmission primarily occurs in the Northeast and upper Midwest, especially parts of New England, New York State, New Jersey, Wisconsin, and Minnesota, blood products collected by blood banks in those areas can be distributed to other regions, increasing the incidence of transfusion—transmitted babesiosis across the United States. Adding babesiosis to the list of reportable

diseases and conditions will improve the ability of public health to identify and respond to transfusion-transmitted infections.

Interferon Gamma Release Assays (IGRA) are blood tests to detect infection with Mycobacterium tuberculosis. Achieving tuberculosis elimination in the United States will require increased attention to targeted testing and treatment of latent tuberculosis infection. Testing people at relatively high risk for tuberculosis and providing preventive treatment to reduce the future risk of becoming sick with tuberculosis is a key focus of the Centers for Disease Control and Prevention and demonstrating progress in this area is a requirement in the latest application for states to obtain federal funding for tuberculosis control. IGRA tests have been recommended as the preferred tests (over the traditional tuberculin skin test) in most people at risk for tuberculosis infection. They have several advantages over the tuberculin skin test, including greater test specificity, less reliance on specialized healthcare worker training to place/read tests, and the need for only a single visit (instead of two visits) to perform the test.

Zika virus infection will be re-listed on the list of reportable diseases and conditions after being inadvertently removed during a previous rule amendment.

Changes related to laboratory reporting are proposed to bring the language in line with current public health recommendations and laboratory procedures, and changes related to disease nomenclature are proposed to bring the language in line with current scientific consensus. These are explained below.

Anaplasmosis and Anaplasma spp., in (a)(3) and in (c)(1)(a):
Anaplasmosis is added because it is the new name for one of the infectious diseases that used to be covered under "Ehrlichiosis."
Many years ago (1996) the case definition for "ehrlichiosis" included illness due to Human Granulocytic Ehrlichiosis (HGE, causative organism at the time unknown, this later became anaplasmosis) and Human Monocytic Ehrlichiosis (HME, due to Ehrlichia chaffensis). Over the years the national case definition and what is notifiable evolved to include two distinct (but related tick borne rickettsial) conditions. Rule .0101 had not yet been adapted to reflect the changes made in the national notifiable disease list. We are proposing this change as one under the "nomenclature" justification, because breaking out "anaplasmosis" as separate is more accurate. Anaplasmosis (or HGE) was always reportable under "ehrlichiosis." It is just that now we are updating the list to reflect what we collectively know about this condition.

Dengue in (c)(1)(S) and in (c)(3)(B)(iv), Chikungunya in (c)(3)(A)(v) and in (c)(3)(B)(ii):
Under the current wording of rule .0101 (for reportable laboratory results) "arthropod borne virus" is a generic name for these viruses. So we are proposing this change as one under the "nomenclature" justification: while these conditions should be reportable under the general heading "arthropod borne virus" we have added them specifically since they have their own entries under the nationally notifiable disease list. Ultimately, they do not represent a new requirement; this change does add some clarity and specificity. The generic "arthropod borne virus" continues to have utility for both our endemic conditions (West Nile Virus, Eastern Equine Encephalitis virus, and LaCrosse encephalitis virus) but also emerging conditions should they be identified in persons living in North Carolina (For example Powassan virus, Heartland virus and Bourbon virus).

Hepatitis A, measles, and mumps are all diseases for which direct identification of the pathogen was historically not something that we could do, and so they were up to now only listed under serologies for laboratory reporting. This is a proposed change that falls under the justification of "scientific progress in laboratory testing." It is time to make these changes as PCR (Polymerase Chain Reaction, a test that amplifies nucleic acid specific to the causative agent) is becoming commonly used. Laboratories are transitioning away from serological testing and directly identifying pathogens via PCR and other molecular tests. These changes are updating the rule to account for current and future changes in laboratory methods, and do not change the workflows for either clinicians or state and local health departments or add anything that was not already reportable under part (a).

The time window for administering vaccination for post-exposure prophylaxis to contacts of measles cases is within three days of exposure. Making measles reportable "immediately" rather than "within 24 hours" will provide additional time for public health case investigation and response.

Public Health Disease Surveillance

The core mission of the Communicable Disease Branch of the NC Division of Public Health Epidemiology Section is to identify, prevent, and control 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. The first step in this process is disease surveillance, which is accomplished by requiring healthcare providers to report diseases and conditions enumerated in the 10A NCAC 41A.

"Disease surveillance is the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control. It provides scientific information that is used for health action by public health personnel, government leaders, and the public to guide public health policy and programs."(Public Health 101 Series, Introduction to Public Health. Surveillance)

By conducting communicable disease surveillance, public health monitors incidence and potential spread to identify any patterns of progression. By observing diseases in their early stages, public health can evaluate the need for potential control measures and then implement these measures before diseases take a foothold. Implementation of early control measures can significantly reduce the burden of disease.

Opportunity Costs

Table 1 shows the total estimated impact of this rule change. The estimates for time spent on the investigations (both public and private) come from time spent on recent case investigations in North Carolina or estimates of case counts based on other states of similar population.

State Agency Impact

The impact on the state agency was estimated based on the mean hourly wage for a State Public Health Epidemiologist of $27.96[1] and for a State DHHS Medical Laboratory Technologist II of $23.03[1], as well as the assumption of the benefits package being about 51.6%[2] and 53.9%[2] of the wage, respectively.

Communicable disease staff are already conducting surveillance for AFM through voluntary reporting from physicians and health care facilities. North Carolina has investigated a total of 20 cases of AFM since voluntary reporting was recommended in 2014. Nine (45%) were confirmed, two (10%) were probable, and nine (45%) did not meet case definition criteria.

States with similar population size and age demographics to North Carolina report approximately 30 cases of varicella each month.

Nationally, from the 33 states where Babesiosis is currently reportable, an average of 1,500 cases are reported per year. However, the vast majority of cases are reported from endemic states in the upper Midwest and New England. In Alabama and Tennessee, which are similar to NC in terms of tick ecology and where Babesiosis is reportable, less than 5 cases per year are reported in each state.

Compared to states which implemented IGRA reporting as part of the mandatory latent TB infection reporting and are similar to North Carolina regarding tuberculosis, approximately 12,000 to 14,000 events are expected to be created in NC EDSS. About 5% or 600 to 700 cases are expected to need closer review from the state epidemiologist and an estimated 10% or 60-70 cases need to be transferred to the local health department staff. The remaining cases require minimal review including deduplication efforts and assessment of completeness.

The proposed amendment will have a fiscal impact on the State Agency. The NC Division of Public Health Information Technology team will update the North Carolina Electronic Disease Surveillance System (NC EDSS) at one-time cost of $2,587.04 for each of the following: AMF, babesiosis, and varicella, for a total of $7,761.12. Since a tuberculosis/latent tuberculosis infection condition already exists in NC EDSS, minimal adjustments to question packages and workflows will be required at an estimated half of the cost of creating a new condition or $1,293.52. The total cost for one-time NC EDSS is therefore $9,054.64. This estimate includes an hourly compensation of $43.70[1] for a DHHS Applications Systems Analyst II, plus 48%[2] in benefits, and time required to develop and implement the necessary updates within the NC EDSS system (about 40 hours per condition as per the Software Delivery Manager, with this time including a 25% increase to account for possible redos).

Local Agency Impact
Local health department staff would spend an increased amount of time on outbreak investigation and response efforts. The impact on the county agencies was estimated based on mean hourly wage of $19.59 for a Public Health Nurse II, obtained from the Public Health Nursing Program in the NC Division of Public Health, as well as an assumption that the benefits package (health, retirement, paid leave, etc.) is similar to what state employees receive and it is about 52% of their wage.[4]

Private-Sector Impact
The proposed amendment will have minimal fiscal impact on the private sector, and would entail actions to report a case (via electronic submission, phone, or paper form) and packaging of specimens.

Electronic submission for IGRA's will have a minimal fiscal impact on the private sector. All pertinent information are already entered into the laboratory system and are able to be extracted and transmitted to NC EDSS once enabled. The cost for the time of the private sector Clinical Laboratory Technologist or Technician and Registered Nurse is based on their wage of $26.79[3] and 32.59[3] respectively, which was obtained from the 2016 State Occupational Employment and Wage Estimates in NC published by the Bureau of Labor Statistics [3] and an assumption of benefits of 48%.

[1] NC state employee salaries https://www.newsobserver.com/news/databases/state-pay/article11865482.html

[2] Total compensation calculator https://oshr.nc.gov/state-employee-resources/classification-compensation/total-compensation-calculator

[3] Bureau of Labor Statistics https://www.bls.gov/oes/current/oes_nc.htm#29-0000

[4] NC Office of State Human Resources. 2015 Compensation and Benefits Report.

Table 1

NC DPH Permanent Reporting of AFM, Babesiosis, Varicella, and Zika

Impact Analysis

Projected Annual Cost

A. Annual Impact on Private Sector

Reportable Condition	# Events Reported	Total Hours per Event Reported	Hourly Salary of Private Sector Registered Nurse	Cost to Private Sector
AFM	5	1	$48	$240
Varicella	360	.5	$48	$8,640
Babesiosis	5	1	$48	$240
Zika	5	1	$48	$240
IGRA	500	.25	$48	$6,000

Reportable Condition	# Events Reported	Total Hours per Event Reported	Hourly Salary of Private Sector Clinical Laboratory Technologist or Technician	Cost to Private Sector
AFM	5	.5	$40	$100
Varicella	360	.5	$40	$7,200
Babesiosis	5	.5	$40	$100
Zika	5	.5	$40	$100
IGRA	13,500	0	$40	$0
			Total Cost to Private Sector	
				$22,860

B. Impact on State Agency: Division of Public Health, Epidemiology Section

Reportable Condition	# Events Reported	Total Hours per Event Reported	Hourly Salary of State Epidemiologist	Cost to State Agency
AFM	5	2	$42	$420
Varicella	360	1	$42	$15,120
Babesiosis	5	1	$42	$210
Zika	5	1	$42	$210
IGRA	700	.5	$42	$14,700

Reportable Condition	# Events Reported	Total Hours per Event Reported	Hourly Salary of Medical Laboratory Technologist II	Cost to State Agency
AFM	5	0	$35	$0
Varicella	360	1	$35	$12,600
Babesiosis	5	0	$35	$0
Zika	5	0	$35	$0

IGRA	700	0	$35	$0
				Total Cost to State Agency
				$43,260

C. Impact on County Agencies: Local Health Department

Reportable Condition	**# Events Reported**	**Total Hours per Event Reported**	**Hourly Salary of Public Health Nurse II at LHD**	**Total Cost to County Agencies**
AFM	5	1	$30	$150
Varicella	360	2	$30	$21,600
Babesiosis	5	1	$30	$150
Zika	5	1	$30	$150
IGRA	70	.5	$30	$1,050
			Total cost to Local Health Departments	
			$23,100	

D. Total Annual Estimated Economic Impact

	Year 1	Year 2 onward
One-time programming cost at state level to make changes to NC EDSS	$9,055	$0
Private Costs Sector	$22,860	$22,860
State Gov't Reporting and Investigation Costs	$43,260	$43,260
Local Gov't Reporting and Investigation Costs	23,100	23,100
Total Costs	**$98,275**	**$89,220**

Note: No cost is assigned in the above tables for IGRA as making the results electronically reportable has no impact on existing processes; and no cost is assigned to changes pertaining to nomenclature and timing changes.

Appendix A:

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

CHAPTER 41 - EPIDEMIOLOGY HEALTH

SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL

SECTION .0100 - COMMUNICABLE DISEASE CONTROL

10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

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

(1) acquired immune deficiency syndrome (AIDS) - 24 hours;

(2) acute flaccid myelitis – 7 days;

(3) anaplasmosis – 7 days;

(4)~~(2)~~ anthrax - immediately;

(5) arboviral infection, neuroinvasive – 7 days;

(6) babesiosis – 7 days;

(7)~~(3)~~ botulism - immediately;

(8)~~(4)~~ brucellosis - 7 days;

(9)~~(5)~~ campylobacter infection - 24 hours;

(10)~~(6)~~ Candida auris xxxxxx - 24 hours;

(11)~~(7)~~ Carbapenem-Resistant Enterobacteriaceae (CRE) xxxxxxx – 24 hours;

(12)~~(8)~~ chancroid - 24 hours;

(13)~~(9)~~ chikungunya virus infection - 24 hours;

(14)~~(10)~~ chlamydial infection (laboratory confirmed) - 7 days;

(15)~~(11)~~ cholera - 24 hours;

(16)~~(12)~~ Creutzfeldt-Jakob disease – 7 days;

(17)~~(13)~~ cryptosporidiosis – 24 hours;

(18)~~(14)~~ cyclosporiasis – 24 hours;

(19)~~(15)~~ dengue - 7 days;

(20)~~(16)~~ diphtheria - 24 hours;

(21)~~(17)~~ Escherichia coli, shiga toxin-producing infection - 24 hours;

(22)~~(18)~~ ehrlichiosis – 7 days;

~~(19) encephalitis, arboviral - 7 days;~~

(23)~~(20)~~ foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes - 24 hours;

(24)~~(21)~~ gonorrhea - 24 hours;

(25)~~(22)~~ granuloma inguinale – 24 hours;

(26)~~(23)~~ Haemophilus influenzae, invasive disease – 24 hours;

(27)~~(24)~~ Hantavirus infection – 7 days;

(28)~~(25)~~ Hemolytic-uremic syndrome – 24 hours;

(29)~~(26)~~ Hemorrhagic fever virus infection – immediately;

(30)~~(27)~~ hepatitis A – 24 hours;

(31)~~(28)~~ hepatitis B – 24 hours;

(32)~~(29)~~ hepatitis B carriage – 7 days;

(33)~~(30)~~ hepatitis C, acute – 7 days;

(34)~~(31)~~ human immunodeficiency virus (HIV) infection confirmed – 24 hours;

(35)~~(32)~~ influenza virus infection causing death – 24 hours;

(36)~~(33)~~ legionellosis – 7 days;

(37)~~(34)~~ leprosy – 7 days;

(38)~~(35)~~ leptospirosis – 7 days;

(39)~~(36)~~ listeriosis – 24 hours;

(40)~~(37)~~ Lyme disease – 7 days;

(41)~~(38)~~ Lymphogranuloma venereum – 7 days;

(42)~~(39)~~ malaria – 7 days;

(43)~~(40)~~ measles (rubeola) – immediately~~24 hours~~;

(44)~~(41)~~ meningitis, pneumococcal – 7 days;

(45)~~(42)~~ meningococcal disease – 24 hours;

(46)~~(43)~~ Middle East respiratory syndrome (MERS) – 24 hours;

(47)~~(44)~~ monkeypox – 24 hours;

(48)~~(45)~~ mumps – 7 days;

(49)~~(46)~~ nongonococcal urethritis – 7 days;

(50)~~(47)~~ novel influenza virus infection – immediately;

(51)~~(48)~~ plague – immediately;

(52)~~(49)~~ paralytic poliomyelitis – 24 hours;

(53)~~(50)~~ pelvic inflammatory disease – 7 days;

(54)~~(51)~~ psittacosis – 7 days;

(55)~~(52)~~ Q fever – 7 days;

(56)~~(53)~~ rabies, human – 24 hours;

~~(54) Rocky Mountain spotted fever – 7 days;~~

(57)~~(55)~~ rubella – 24 hours;

(58)~~(56)~~ rubella congenital syndrome – 7 days;

(59)~~(57)~~ salmonellosis – 24 hours;

(60)~~(58)~~ severe acute respiratory syndrome (SARS) – 24 hours;

(61)~~(59)~~ shigellosis – 24 hours;

(62)~~(60)~~ smallpox ‑ immediately;

(63) spotted fever rickettsiosis – 7 days;

(64)~~(61)~~ Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;

(65)~~(62)~~ streptococcal infection, Group A, invasive disease ‑ 7 days;

(66)~~(63)~~ syphilis ‑ 24 hours;

(67)~~(64)~~ tetanus ‑ 7 days;

(68)~~(65)~~ toxic shock syndrome ‑ 7 days;

(69)~~(66)~~ trichinosis ‑ 7 days;

(70)~~(67)~~ tuberculosis ‑ 24 hours;

(71)~~(68)~~ tularemia – immediately;

(72)~~(69)~~ typhoid ‑ 24 hours;

(73)~~(70)~~ typhoid carriage (Salmonella typhi) ‑ 7 days;

(74)~~(71)~~ typhus, epidemic (louse-borne) ‑ 7 days;

(75)~~(72)~~ vaccinia – 24 hours;

(76) varicella – 24 hours;

(77)~~(73)~~ vibrio infection (other than cholera) – 24 hours;

(78)~~(74)~~ whooping cough – 24 hours; ~~and~~

(79)~~(75)~~ yellow fever – 7 days; ~~days.~~ and

(80) zika virus – 24 hours.

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

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

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

(A) Anaplasma spp, the causes of anaplasmosis.

(B) Any hantavirus or hemorrhagic fever virus.

(C)~~(B)~~ Arthropod-borne virus (any type).

(D) Babesia spp., the cause of babesiosis.

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

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

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

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

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

(J)~~(H)~~ Candida auris.

(K)~~(I)~~ Carbapenem-Resistant Enterobacteriaceae (CRE).

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

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

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

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

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

(Q)~~(O)~~ Cryptosporidium spp.~~parvum~~, the cause of human cryptosporidiosis.

(R)~~(P)~~ Cyclospora cayetanesis, the cause of cyclosporiasis.

(S) Dengue virus.

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

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

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

(W) Hepatitis A virus.

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

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

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

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

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

(CC) Measles virus.

(DD)~~(Y)~~ Middle East respiratory syndrome virus.

(EE)~~(Z)~~ Monkeypox.

(FF) Mumps virus.

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

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

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

(JJ)~~(DD)~~ Rabies virus.

(KK)~~(EE)~~ Rickettsia spp.~~rickettsii~~, the cause of ~~Rocky Mountain~~ spotted fever rickettsiosis.

(LL)~~(FF)~~ Rubella virus.

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

(NN)~~(HH)~~ Shigella spp., the causes of shigellosis.

(OO)~~(II)~~ Smallpox virus, the cause of smallpox.

(PP)~~(JJ)~~ Staphylococcus aureus with reduced susceptibility to vanomycin.

(QQ)~~(KK)~~ Trichinella spiralis, the cause of trichinosis.

(RR)~~(LL)~~ Vaccinia virus.

(SS) Varicella virus.

(TT)~~(MM)~~ Vibrio spp., the causes of cholera and other vibrioses.

(UU)~~(NN)~~ Yellow fever virus.

(VV)~~(OO)~~ Yersinia pestis, the cause of plague.

(WW) Zika virus.

(2) Isolation or other specific identification of the following organisms from normally sterile human body sites:

(A) Group A Streptococcus pyogenes (group A streptococci).

(B) Haemophilus influenzae, serotype b.

(C) Neisseria meningitidis, the cause of meningococcal disease.

(3) Positive serologic test results, as specified, for the following infections:

(A) Fourfold or greater changes or equivalent changes in serum antibody titers to:

(i) Any arthropod-borne virus~~es~~ associated with neuroinvasive disease~~meningitis or encephalitis in a human~~.

(ii) Anaplasma spp., the cause of anaplasmosis.

(iii)~~(ii)~~ Any hantavirus or hemorrhagic fever virus.

(iv)~~(iii)~~ Chlamydia psittaci, the cause of psittacosis.

(v) Chikungunya virus.

(vi)~~(iv)~~ Coxiella burnetii, the cause of Q fever.

(vii)~~(v)~~ Dengue virus.

(viii)(vi) Ehrlichia spp., the causes of ehrlichiosis.

(ix)~~(vii)~~ Measles (rubeola) virus.

(x)~~(viii)~~ Mumps virus.

(xi)~~(ix)~~ Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.

(xii)~~(x)~~ Rubella virus.

(xiii) Varicella virus.

(xiv)~~(xi)~~ Yellow fever virus.

(B) The presence of IgM serum antibodies to:

(i) Any arthropod-borne virus associated with neuroinvasive disease.

(ii) Chikungunya virus.

(iii)~~(i)~~ Chlamydia psittaci.

(iv) Dengue virus.

(v)~~(ii)~~ Hepatitis A virus.

(vi)~~(iii)~~ Hepatitis B virus core antigen.

(vii) Mumps virus.

(viii)~~(iv)~~ Rubella virus.

(ix)~~(v)~~ Rubeola (measles) virus.

(x)~~(vi)~~ Yellow fever virus.

(4) Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4) subset of lymphocytes and all results from tests to determine HIV viral load.

(5) Identification of CRE from a clinical specimen associated with either infection or colonization, including all susceptibility results and all phenotypic or molecular test results.

(d) Laboratories utilizing electronic laboratory reporting (ELR) shall report in addition to those listed under Paragraph (c) of this Rule:

(1) All positive laboratory results from tests used to diagnosis chronic Hepatitis C Infection, including the following:

(A) Hepatitis C virus antibody tests (including the test specific signal to cut-off (s/c) ratio);

(B) Hepatitis C nucleic acid tests;

(C) Hepatitis C antigen(s) tests; and

(D) Hepatitis C genotypic tests.

(2) All HIV genotypic test results, including when available:

(A) The entire nucleotide sequence; or

(B) The pol region sequence (including all regions: protease (PR)/reverse transcriptase (RT) and integrase (INI) genes, if available).

(3) All test results for Interferon Gamma Release Assays.

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

(1) Enterobacter spp, E.coli or Klebsiella spp positive for a known carbapenemase resistance mechanism or positive on a phenotypic test for carbapenemase production; or

(2) Enterobacter spp, E.coli or Klebsiella spp resistant to any carbapenem in the absence of carbapenemase resistance mechanism testing or phenotypic testing for carbapenemase production.

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