Impact Analysis for Amendment of 10A NCAC 41A .0101 to add CPO and Cronobacter

Agency:	NC Commission for Public Health NC Department of Health and Human Services Epidemiology Section, Communicable Disease Branch
Rule Citation(s):	10A NCAC 41A .0101
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Rulemaking Authority:	N.C.G.S. 130A-134; 130A-135; 130A-139; 130A-141
Impact Summary:	State Government: Yes Local Government: Yes Private Entities: Yes Substantial Impact: No

Introduction and Purpose

This fiscal note analyzes the impact of proposed changes to 10A NCAC 41A .0101 to add the reporting of carbapenemase-producing organisms (CPO) and Cronobacter and make other technical updates.

Carbapenemase-producing organisms (CPO)

As of 2019, the CDC has listed both carbapenem-resistant Enterobacteriaceae (CRE) and carbapenem-resistant *Acinetobacter* as urgent public health threats and carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) as a serious public health threat.[1] This fiscal note analyzes the impact of expanding the current 10A NCAC 41A .0101 CRE reporting requirement to all Carbapenemase-Producing Organisms (CPO). Under the current CRE reporting requirement, only isolates of *Enterobacter* spp., *E. coli* or *Klebsiella* spp. positive for a known carbapenemase production (or carbapenem-resistant in the absence of carbapenemase testing) are reportable in North Carolina. In alignment with the 2022 Council for State and Territorial Epidemiologists (CSTE) position statement,[2] this rule change will expand the requirement to all isolates that produce carbapenemase, regardless of the organism. Reporting of CPO will facilitate proactive containment of existing and new antimicrobial threats.

Cronobacter

Cronobacter species, (including *C. sakazakii* and generically referred to as "Cronobacter") a species of gram-negative bacteria belonging to the Enterobacteriaceae family, is known to cause severe and often fatal meningitis

[1] Centers for Disease Control and Prevention. 2019. Antibiotic Resistance Threats in the United States. https://ndc.services.cdc.gov/wp-content/uploads/Antibiotic-Resistance-Threats-in-the-United-States-2019.pdf

[2] Council of State and Territorial Epidemiologists (CSTE). 2022. Change in Case Definition from Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) to Carbapenemase-Producing Organisms (CPO). https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/ps2022/22-ID-04_CPO.pdf

and sepsis in young infants (up to 40% case fatality rate). Cronobacter is ubiquitous in the environment, and most reported infant cases have been attributed to contaminated powdered infant formula (PIF) or breast milk that was expressed using contaminated breast pump equipment. However, Cronobacter infection has not been nationally notifiable until 2024, and is only legally reportable in a handful of states. Recently, the Council of State and Territorial Epidemiologists (CSTE) recommended that all states enact requirements to make invasive Cronobacter infections among infants (less than 12 months of age) reportable. This fiscal note analyzes the impact of adding Cronobacter to 10A NCAC 41A .0101 in alignment with the CSTE recommendation. Reporting of Cronobacter will facilitate thorough case investigation and support a coordinated response among state and federal agencies to prevent and contain outbreaks.

Description of Proposed Rules

The two primary proposed amendments to rule 10A NCAC 41A .0101 are to make CPO and Cronobacter reportable. There are also several small technical updates, discussed below. A copy of the proposed rule text is attached in the **Appendix**.

CPO

The first primary amendment is to expand from requiring the reporting of carbapenem-resistant enterobacteriaceae (CRE) to the reporting of all Carbapenemase-Producing Organisms (CPO). This will include all isolates with the identification of carbapenemase-production from a specimen associated with either infection or colonization, all susceptibility results, and all phenotypic, molecular, or sequencing test results.

Cronobacter infection

The second primary amendment is to add a reporting requirement for invasive Cronobacter infections in individuals less than 12 months of age. Isolation by culture of Cronobacter spp. in a clinical specimen from a normally sterile site (e.g., blood or cerebrospinal fluid) or from a non-sterile site (e.g., stool or rectum, urine, skin, respiratory secretions, or broncho-alveolar lavage, etc.) will be reportable.

Technical Updates

Two technical amendments within the rule have been made to correct existing language. Monkeypox has been updated to current term “mpox.” Also, typhoid carriage has been deleted from the reportable conditions list and the term typhoid has been differentiated into the two types of bacteria that cause typhoid: *Salmonella* Typhi and *Salmonella* Paratyphi. There are a very small number of S. Typhi and S. Paratyphi cases in North Carolina, mostly due to travel associated illness. As such, little to no impact is anticipated as a result of these technical updates and they are not further discussed in this fiscal note.

Impact Analysis

Costs

The estimated cost for these amendments is detailed in **Table 1** below.

Based on experience with reporting of CRE and current surveillance levels in North Carolina and surrounding states, it is estimated that there will be approximately 338 cases of CPO in North Carolina that are required to be reported to public health each year. It is anticipated that the number of cases of CPO will increase over time, but we cannot predict by how much. The surveillance of CPO and resulting preventive and containment measures are expected to help prevent a precipitous rise in cases.

The incidence of invasive Cronobacter infection among infants in the U.S. is estimated to be 0.49 cases/100,000 infants, or approximately 19-20 cases annually, although cases are likely underreported.[3,4] Based on this, it is estimated that there will be approximately 2 cases of Cronobacter in North Carolina that are required to be reported to public health each year. It is anticipated that the number of cases will remain low over time and may decrease with surveillance and resulting preventive and containment measures.

These case levels were used to estimate the cost to state government, local government, and the private sector in Table 1. The estimates in Table 1 for time spent on the investigations (both public and private) come from time spent on recent case investigations in North Carolina or estimates based on other states of similar population.

Private Sector Impact
The proposed amendment will have a small fiscal impact on the private sector that entails actions to report a case (via electronic submission, phone, or paper form). This will involve time spent by laboratory staff (most likely medical laboratory technicians) and by providers (most likely registered nurses) and will be similar to reporting practices for other reportable diseases. The cost for the time of the private sector Laboratory Technicians and Registered Nurses is based on their hourly cost (salary plus benefits) of $35.48[5] and $53.01,[6] respectively.

Local Government Impact
It is anticipated that due to these additional reporting requirements, local health department staff will spend an increased amount of time on outbreak investigation and response efforts. The opportunity cost impact on local government has been estimated based on average salary for a Public Health Nurse II.[7] This salary is $61,988 with fringe benefits estimated at 38.2%[8] which, based on a 40-hour work week, comes to a calculated hourly rate of $41.18.

State Government Impact
Events will be investigated and responded to by the Communicable Disease Branch at the state level, in collaboration with the local health department. The opportunity cost impact on state government has been estimated based on the salary of a state Public Health Epidemiologist, which under NC classification and compensation policies has a mid-point of $71,133. Using this figure, as well as an estimate of the value of fringe benefits,[9] this has a calculated hourly rate of $51.48.

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[3] Kalyantanda, G., Shumyak, L., & Archibald, L. K. (2015). Cronobacter species contamination of powdered infant formula and the implications for neonatal health. Frontiers in Pediatrics, 3. https://doi.org/10.3389/fped.2015.00056.
[4] Patrick M. E., et al. (2014) Patrick ME, Mahon BE, Greene SA, Rounds J, Cronquist A, Wymore K, Boothe E, Lathrop S, Palmer A, Bowen A. Incidence of Cronobacter spp. infections, United States, 2003-2009. Emerg Infect Dis. 2014 Sep;20(9):1520-3. doi: 10.3201/eid2009.140545. PMID: 25148394.
[5] The hourly rate for clinical laboratory technologists and technicians ($27.40) is based the mean hourly wage from the North Carolina State Occupational Employment and Wage Estimates reported by the U.S. Bureau of Labor Statistics (May 2023), available at: https://www.bls.gov/oes/current/oes_nc.htm. The value of benefits was identified using the U.S. Bureau of Labor Statistics' latest available figures from December 2023 on employer costs for employee compensation for private industry workers in the health care industry (29.5%), which is available at: https://www.bls.gov/news.release/ecec.t04.htm.
[6] The hourly rate for a registered nurse ($39.68) is based the mean hourly wage from the North Carolina State Occupational Employment and Wage Estimates reported by the U.S. Bureau of Labor Statistics (May 2023), available at: https://www.bls.gov/oes/current/oes_nc.htm. The value of benefits was identified using the U.S. Bureau of Labor Statistics' latest available figures from December 2023 on employer costs for employee compensation for registered nurses (33.6%), which is available at: https://www.bls.gov/news.release/ecec.t04.htm.
[7] The average Public Health Nurse II salary was estimated using the UNC School of Government's County Salary Survey for 2023, which is available at: https://www.sog.unc.edu/publications/reports/county-salaries-north-carolina-2023.
[8] The value of benefits was identified using the U.S. Bureau of Labor Statistics' latest available figures from December 2023 on employer costs for employee compensation for state and local government workers, which is available at: https://www.bls.gov/news.release/ecec.t03.htm.
[9] The benefits listed were identified using the North Carolina Office of State Human Resources "Total Compensation Calculator," which is available at https://oshr.nc.gov/state-employee-resources/classification-compensation/total-compensation-calculator.

In addition, there will be a one-time cost for an update to the North Carolina Electronic Disease Surveillance System (NC EDSS) to enable electronic reporting and surveillance of these diseases. An IT Programmer with knowledge of Rhapsody programming will be needed to make the necessary updates. The opportunity cost impact on state government has been estimated based on the salary of a state Applications Systems Analyst II, which under NC classification and compensation policies has a mid-point of $94,768. Using this figure, as well as an estimate of the value of fringe benefits,[10] this has a calculated hourly rate of $67.62.

Table 1 – Estimated Opportunity Costs

Estimated Annual Opportunity Costs				
Impact to Private Sector				
Reportable Condition	**# Events Reported**	**Total Hours per Reported Event**	**Hourly Cost of Private Sector Registered Nurse**	**Estimated Cost to Private Sector**
CPO	338	1.5	$53.01	$26,876.07
Cronobacter	2	1.5	$53.01	$159.03
Reportable Condition	**# Events Reported**	**Total Hours per Reported Event**	**Hourly Cost of Private Sector Laboratory Technician**	**Estimated Cost to Private Sector**
CPO	338	1	$35.48	$11,992.24
Cronobacter	2	.5	$35.48	$35.48
Total Annual Opportunity Cost – Private Sector				$39,062.82

Impact to Local Government				
Reportable Condition	**# Events Reported**	**Total Hours per Reported Event**	**Hourly Cost of Public Health Nurse II at LHD**	**Estimated Cost to Local Government**
CPO	338	1	$41.18	$13,918.84
Cronobacter	2	1	$41.18	$82.36
Total Annual Opportunity Cost – Local Government				$14,001.20

Impact to State Government				
Reportable Condition	**# Events Reported**	**Total Hours per Reported Event**	**Hourly Cost of Public Health Epidemiologist**	**Estimated Cost to State Government**
CPO	338	1.5	$51.48	$26,100.36
Cronobacter	2	1.5	$51.48	$154.44
Total Annual Opportunity Cost – State Government				$26,254.80

Estimated One-Time Opportunity Costs			
Impact to State Government			
Task	**Total Hours**	**Hourly Cost of Applications Systems Analyst II**	**Estimated Cost to State Government**
Update to NCEDSS	120	67.62	$8,114.40
Total One-Time Opportunity Cost – State Government			$8,114.40

[10] The benefits listed were identified using the North Carolina Office of State Human Resources "Total Compensation Calculator," which is available at https://oshr.nc.gov/state-employee-resources/classification-compensation/total-compensation-calculator.

Total Estimated Opportunity Costs		
	Year 1	**Year 2 onward**
Private Sector Costs	$39,062.82	$39,062.82
Local Government Costs	$14,001.20	$14,001.20
State Government Costs	$34,369.20	$26,254.80
Total Costs	$87,433.22	$79,318.82

Benefits

There are significant public health benefits to the reporting of CPO and Cronobacter.

CPO

CPO represents a group of multiple antibiotic resistant organisms that are a threat to public health and this threat is growing stronger. For example, carbapenem-resistant *Acinetobacter* was listed by the CDC in 2013 as a serious threat. In 2019, CDC escalated carbapenem-resistant *Acinetobacter* to an urgent threat due to the emergence of easily spread resistance in *Acinetobacter* and the lack of current antibiotics, and the antibiotics in development, to treat these infections. Infections caused by CPO are difficult to treat due to the lack of effective antibiotics. Many CPO are resistant to all available antibiotics. CPO are associated with high mortality, increased lengths of stay in healthcare facilities and higher healthcare costs. In 2017, $130 million in healthcare costs was estimated to be attributable to CRE, $281 million to carbapenem-resistant *Acinetobacter* and $767 million to CRPA.[11]

These organisms produce carbapenemase resistance mechanisms which can spread carbapenem resistance to other organisms, even between species. Approximately 30% of CRE and 2-3% of CRPA carry a carbapenemase gene; one study showed approximately 79% of carbapenem-resistant *Acinetobacter baumanii* (CRAB) isolates carried a carbapenemase gene.[12] Therefore, it is crucial to standardize surveillance to all organisms possibly carrying carbapenemases.

This definition expansion is in accordance with the CSTE position statement released in 2022. CSTE emphasizes the value of expanding this epidemiologically important definition to create a uniform classification of CPO surveillance across public health jurisdictions and create actionable epidemiology of CPO to enable effective prevention, detection and response to these organisms. Surveillance data is used to inform interventions that prevent and reduce spread, which is also anticipated to have the benefit of reducing healthcare costs.

Cronobacter

Although *Cronobacter spp.* have been detected in other food products, the environment, and in some infected infants that did not consume PIF, contaminated PIF has been linked to nearly all Cronobacter infections for which a source was found.[13] In 2001, the U.S. FDA investigated contamination of PIF products following a fatal infection attributed to C. sakazakii and use of PIF in a Tennessee hospital with one case of meningitis and eight additional cases of *C. sakazakii* colonization.[14] Since 2002, the FDA has recommended only ready-to-feed liquid formula for hospitalized neonates; however, despite this recommendation, Cronobacter infections continue to occur in the hospital setting. This suggests an additional need to address infection control issues and hand hygiene, handling

[11] Centers for Disease Control and Prevention. 2019. Antibiotic Resistance Threats in the United States. (footnote 1)
[12] Centers for Disease Control and Prevention. August 2021. Carbapenem-resistant Acinetobacter baumannii (CRAB): An urgent public health threat in United States healthcare facilities. https://arpsp.cdc.gov/story/cra-urgent-public-health-threat
[13] Centers for Disease Control and Prevention. (2017, July 18). Notes from the field: Cronobacter sakazakii infection associated with feeding extrinsically contaminated expressed human milk to a premature infant - Pennsylvania, 2016. Centers for Disease Control and Prevention https://www.cdc.gov/mmwr/volumes/66/wr/mm6628a5.htm.
[14] Centers for Disease Control and Prevention. (n.d.). Enterobacter sakazakii infections associated with the use of powdered infant formula --- Tennessee, 2001. Centers for Disease Control and Prevention. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5114a1.htm

and storage practices, and implementation of safer alternatives to PIF.[15,16] Neonates and infants are at greatest risk for high morbidity and mortality due to their immature immune systems.

Intrinsic contamination of PIF can occur at any stage of manufacturing at the factory before distribution of product for retail. Extrinsic contamination can occur once the container is opened by the user at any stage of reconstitution through contaminated water, utensils, work surfaces; at the time of feeding (e.g., using contaminated feeding bottles or enteral tubing with existing biofilm); or because of inappropriate storage conditions (e.g., poor refrigeration or storage for too long at room temperature). Cronobacter can still be present in PIF despite FDA regulations requiring end-product testing as the pathogen may be non-homogenously distributed in the PIF due to clumping of the product.[17] Given the limitations of end-product testing and the opportunity for extrinsic contamination post-production, public health surveillance is necessary.[18]

Rapid and accurate pathogen identification and speciation is vital for effective public health surveillance and outbreak detection. Unlike most foodborne pathogens, Cronobacter infections are not required to be reported, except in Minnesota and Michigan (as of April 2023); therefore, standardized epidemiological information is not captured to inform prevention efforts, and true incidence of invasive Cronobacter infection among infants is unknown.[9] Standardized surveillance for Cronobacter is necessary to help estimate incidence, identify risk factors, promptly detect and trace outbreaks, and inform control and prevention measures. These public health interventions are used to prevent and reduce Cronobacter outbreaks, which are also anticipated to reduce healthcare costs and save lives.

Summary

The expansion of reporting to include CPO and Cronobacter are supported nationally and evidenced to support public health efforts to prevent, detect, investigate, and control outbreaks of these diseases. The total estimated annual opportunity cost of $79,318.82 and additional one-time opportunity cost of $8,114.40 are small opportunity costs when compared to the public health benefits of detecting and preventing these diseases, including reducing the risk of infants being exposed to contaminated food products and healthcare savings in the treatment of CPO conditions.

[15] Strysko, J., Cope, J. R., Martin, H., Tarr, C., Hise, K., Collier, S., & Bowen, A. (2020). Food safety and invasive Cronobacter infections during early infancy, 1961–2018. Emerging Infectious Diseases, 26(5), 857–865. https://doi.org/10.3201/eid2605.190858.
[16] Kalyantanda, G., Shumyak, L., & Archibald, L. K. (2015). (footnote 3)
[17] Kalyantanda, G., Shumyak, L., & Archibald, L. K. (2015). (footnote 3)
[18] Abebe GM (2020) Cronobacter sakazakii in Infant food Contamination and Its Survival Strategies in Hostile Conditions. Int J Pediatr Res 6:067. doi.org/10.23937/2469-5769/1510067.

Appendix: Proposed Rule Text

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) anthrax - immediately;

(5) arboviral infection, neuroinvasive – 7 days;

(6) babesiosis – 7 days;

(7) botulism - immediately;

(8) brucellosis - 7 days;

(9) campylobacter infection - 24 hours;

(10) Candida auris - 24 hours;

(11) ~~Carbapenem-Resistant Enterobacteriaceae (CRE)~~ Carbapenemase-producing organisms (CPO) – 24 hours;

(12) chancroid - 24 hours;

(13) chikungunya virus infection - 24 hours;

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

(15) cholera - 24 hours;

(16) Creutzfeldt-Jakob disease – 7 days;

(17) cronobacter infection, invasive, in individuals less than twelve months of age – 24 hours;

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

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

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

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

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

(23)~~(22)~~ ehrlichiosis – 7 days;

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

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

(26)~~(25)~~ granuloma inguinale - 24 hours;

(27)~~(26)~~ Haemophilus influenzae, invasive disease ‑ 24 hours;

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

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

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

(31)~~(30)~~ hepatitis A ‑ 24 hours;

(32)~~(31)~~ hepatitis B ‑ 24 hours;

(33)~~(32)~~ hepatitis B carriage ‑ 7 days;

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

(35)~~(34)~~ human immunodeficiency virus (HIV) infection confirmed ‑ 24 hours;

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

(37)~~(36)~~ legionellosis ‑ 7 days;

(38)~~(37)~~ leprosy – 7 days;

(39)~~(38)~~ leptospirosis ‑ 7 days;

(40)~~(39)~~ listeriosis – 24 hours;

(41)~~(40)~~ Lyme disease ‑ 7 days;

(42)~~(41)~~ Lymphogranuloma venereum ‑ 7 days;

(43)~~(42)~~ malaria ‑ 7 days;

(44)~~(43)~~ measles (rubeola) ‑ immediately;

(45)~~(44)~~ meningitis, pneumococcal ‑ 7 days;

(46)~~(45)~~ meningococcal disease ‑ 24 hours;

(47)~~(46)~~ Middle East respiratory syndrome (MERS) ‑ 24 hours;

(48)~~(47)~~ ~~monkeypox~~ mpox – 24 hours;

(49)~~(48)~~ mumps ‑ 7 days;

(50)~~(49)~~ nongonococcal urethritis ‑ 7 days;

(51)~~(50)~~ novel coronavirus infection causing death – 24 hours;

(52)~~(51)~~ novel coronavirus infection – immediately;

(53)~~(52)~~ novel influenza virus infection – immediately;

(54)~~(53)~~ plague ‑ immediately;

(55)~~(54)~~ paralytic poliomyelitis ‑ 24 hours;

(56)~~(55)~~ pelvic inflammatory disease – 7 days;

(57)~~(56)~~ psittacosis ‑ 7 days;

(58)~~(57)~~ Q fever ‑ 7 days;

(59)~~(58)~~ rabies, human ‑ 24 hours;

(60)~~(59)~~ rubella ‑ 24 hours;

(61)~~(60)~~ rubella congenital syndrome ‑ 7 days;

(62)~~(61)~~ salmonellosis ‑ 24 hours;

(63) salmonella typhi infection – 24 hours;

(64) salmonella paratyphi infection – 24 hours;

(65)~~(62)~~ severe acute respiratory syndrome (SARS) – 24 hours;

(66)~~(63)~~ shigellosis - 24 hours;

(67)~~(64)~~ smallpox - immediately;

(68)~~(65)~~ spotted fever rickettsiosis – 7 days;

(69)~~(66)~~ Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;

(70)~~(67)~~ streptococcal infection, Group A, invasive disease - 7 days;

(71)~~(68)~~ syphilis - 24 hours;

(72)~~(69)~~ tetanus - 7 days;

(73)~~(70)~~ toxic shock syndrome - 7 days;

(74)~~(71)~~ trichinosis - 7 days;

(75)~~(72)~~ tuberculosis - 24 hours;

(76)~~(73)~~ tularemia – immediately;

~~(74) typhoid - 24 hours;~~

~~(75) typhoid carriage (Salmonella typhi) - 7 days;~~

(77)~~(76)~~ typhus, epidemic (louse-borne) - 7 days;

(78)~~(77)~~ vaccinia – 24 hours;

(79)~~(78)~~ varicella – 24 hours;

(80)~~(79)~~ vibrio infection (other than cholera) – 24 hours;

(81)~~(80)~~ whooping cough – 24 hours;

(82)~~(81)~~ yellow fever – 7 days; and

(83)~~(82)~~ 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.

(C) Any hemorrhagic fever virus.

(D) Arthropod-borne virus (any type).

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

(F) Bacillus anthracis, the cause of anthrax.

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

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

(I) Brucella spp., the causes of brucellosis.

(J) Campylobacter spp., the causes of campylobacteriosis.

(K) Candida auris.

(L) ~~Carbapenem-Resistant Enterobacteriaceae (CRE).~~ Carbapenemase-producing organisms (CPO).

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

(N) Clostridium botulinum, a cause of botulism.

(O) Clostridium tetani, the cause of tetanus.

(P) Coronavirus, novel human strain.

(Q) Corynebacterium diphtheriae, the cause of diphtheria.

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

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

(T) Cyclospora cayetanensis, the cause of cyclosporiasis.

(U) Dengue virus.

(V) Ehrlichia spp., the causes of ehrlichiosis.

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

(X) Francisella tularensis, the cause of tularemia.

(Y) Hepatitis A virus.

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

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

(BB) Legionella spp., the causes of legionellosis.

(CC) Leptospira spp., the causes of leptospirosis.

(DD) Listeria monocytogenes, the cause of listeriosis.

(EE) Measles virus.

(FF) Middle East respiratory syndrome virus.

(GG) ~~Monkeypox.~~ Mpox.

(HH) Mumps virus.

(II) Mycobacterium leprae, the cause of leprosy.

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

(KK) Poliovirus (any), the cause of poliomyelitis.

(LL) Rabies virus.

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

(NN) Rubella virus.

(OO) Salmonella spp., the causes of ~~salmonellosis.~~ salmonellosis, s. typhi infection, and s. paratyphi infection.

(PP) Shigella spp., the causes of shigellosis.

(QQ) Smallpox virus, the cause of smallpox.

(RR) Staphylococcus aureus with reduced susceptibility to vancomycin.

(SS) Trichinella spiralis, the cause of trichinosis.

(TT) Vaccinia virus.

(UU) Varicella virus.

(VV) Vibrio spp., the causes of cholera and other vibrioses.

(WW) Yellow fever virus.

(XX) Yersinia pestis, the cause of plague.

(YY) Zika virus.

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

(A) Cronobacter spp., if isolated or identified from individuals less than twelve months of age.

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

~~(B)~~(C) Haemophilus influenzae, serotype b.

~~(C)~~(D) 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 associated with neuroinvasive disease.

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

(iii) Any hantavirus or hemorrhagic fever virus.

(iv) Chlamydia psittaci, the cause of psittacosis.

(v) Chikungunya virus.

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

(vii) Dengue virus.

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

(ix) Measles (rubeola) virus.

(x) Mumps virus.

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

(xii) Rubella virus.

(xiii) Varicella virus.

(xiv) Yellow fever virus.

(B) The presence of IgM serum antibodies to:

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

(ii) Chikungunya virus.

(iii) Chlamydia psittaci.

(iv) Dengue virus.

(v) Hepatitis A virus.

(vi) Hepatitis B virus core antigen.

(vii) Mumps virus.

(viii) Rubella virus.

(ix) Rubeola (measles) virus.

(x) 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~~ CPO 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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