

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

Requires OSBM Review - Seeking Fast-Track Approval

Agency: 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 (c)(4) REPORTABLE DISEASES AND CONDITIONS

Purpose of Rule Change:

10A NCAC 41A .0101 (c)(4): Modify the rule regarding the minimum value of CD4 (T-helper lymphocytes) to indicate that all CD4 results are reportable by laboratories and indicate that all HIV viral load results, including an undetectable level, are reportable.

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

State Impact:	Yes
Local Government Impact:	No
Private-Sector Impact	Yes
Substantial Economic Impact:	No
Significant Rule Change:	No

Background

In order to provide quality HIV care and to respond to the President's National HIV/AIDS Strategy,¹ the public health agencies of the nation must ensure that there is an effective and accurate mechanism to monitor whether persons living with HIV are accessing resources for care for their disease. Two criteria that are expected by the federal government agencies (e.g. Centers for Disease Control and Prevention and Health Resources and Services Administration) to be performed by state public health agencies are the monitoring of all helper T-cell (CD4) counts and the ability to determine whether a patient has a detectable HIV viral load.

Successful management of HIV infection should result in a person's CD4 counts remaining in a near normal range (relative to a non-infected person) while also having a non-detectable HIV viral load. Also, as a result of a recent clinical trial (the HTPN 052 trial), we know that HIV-infected persons with a non-detectable viral load are extremely unlikely to transmit HIV to their partners. Ongoing assessment of HIV viral loads and CD4 tests therefore enable a mechanism to possibly indicate whether a client has received regular HIV care visits and to provide the results of such visits that inform our understanding of viral suppression and relative immune system status.

The Division of Public Health's experience over the past decade is that the Division has missed identification of some patients who are receiving care for HIV infection in NC but who have CD4 counts greater than the current reporting requirement. Being unaware of these laboratory results hampers the Division's surveillance of disease progression in patients living with HIV/AIDS. This is especially true for persons who may have moved to NC subsequent to a diagnosis with HIV in another state but who are now receiving services in NC and are unknown

¹ See <http://www.whitehouse.gov/administration/eop/onap/nhas>

to the Division's HIV surveillance system. Since the Division has no knowledge of these clients, we are unable to respond appropriately as these patients drop out of the HIV care system. The Division has an initial CD4 result reported to the Division's surveillance office for approximately half of the recently diagnosed persons with HIV, making establishment of the baseline CD4 level problematic. Implementation of a rule requiring reporting for all CD4 results will improve the Division's initial assessment of CD4 levels and the assessment of immune system status at the time of initial identification with HIV infection, as well as disease progression.

The reporting of all viral load results is also an important factor in the Division's ability to assess whether patients are receiving appropriate care and to assist in the Division's assessment of community viral load evaluation to improve our targeting of HIV prevention activities. North Carolina is one of three "medium to high" HIV morbidity states without regulations requiring all CD4 and all viral load result reporting. In all of the recent Federal Funding Opportunity Announcements issued by both the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) related to HIV surveillance or HIV prevention activities, an expectation for funding has been that regulations requiring the laboratory reporting of all CD4 and all viral load results must be in place or in preparation.

Beyond the expectations from the CDC and HRSA for changing regulations to support universal viral load reporting, it is in North Carolina's best interest to enhance the Division's ability to monitor how successful our systems are to link HIV-positive individuals to appropriate care and how those patients respond with respect to viral suppression for HIV. Within the Communicable Disease Branch, we have several new initiatives to monitor laboratory testing (and the results of those tests) that suggest a patient is in care. An absence of expected routine laboratory tests reported would suggest that the patient may no longer be receiving care. The key in all of the initiatives is collection of all viral load and CD4 results. The key National HIV/AIDS Strategy (NHAS) marker indicating success is that patients have an HIV viral load of less than 200 copies/mL. In North Carolina, at this time, we estimate that approximately 30% of the patients for whom we receive viral load laboratory reports meet this viral suppression expectation. We understand that we are likely missing viral load results for patients where the testing is conducted by laboratories that do not voluntarily report all viral load results. Thus our estimate of suppression may be low.

One mechanism used to describe and evaluate the need for improvement in HIV service delivery has been the continuum of care diagram or so-called "Gardner cascade" that seeks to estimate how service delivery is lost following initial diagnosis with HIV. The Division has developed a preliminary NC version of the cascade that is still being improved by including additional data sources, but we believe this represents the worst case scenario of what we understand for viral suppression at this time. The Division's approach was to generate our cascade or continuum to try to indicate change over time rather than a single estimate as most others have done. We have included both the national cascade as published in December 2011 in the CDC's Morbidity and Mortality Weekly Report (MMWR) and our version at the end of this document.

About the North Carolina Communicable Disease Branch

The Communicable Disease Branch is located within the Epidemiology Section of the Division of Public Health. The goal of the Communicable Disease Branch is to conduct surveillance activities for communicable diseases, including HIV and other STDs, and other diseases reportable under NC law, and to protect the health of the citizens of North Carolina through prevention and control of those diseases. Branch staff review case report data and assist local health directors and others investigate disease cases and outbreaks, determine appropriate control measures to help prevent disease transmission, and ensure that these control measures are applied. The Branch is also responsible for monitoring health data from hospital emergency departments, poison center calls, ambulance data, and other sources to detect diseases that may result from terrorism and for providing situational awareness during disease outbreaks and natural or man-made disasters. In addition, the AIDS care component of the Branch ensures that HIV/AIDS-infected individuals are able to access a continuum of care services, including case management, medical and dental care, complicated and expensive medications regimens, housing, and a full range of ancillary services.

Impact Analysis

The proposed modifications should have no measurable fiscal impact on physicians, other healthcare providers, or healthcare facilities other than laboratories performing the specified laboratory tests. This rule change does not require communicable disease staff at local health departments to spend time in any investigation or reporting activity from reports received. The proposed amendment to this rule does not create a new reporting requirement for laboratories other than expanding the range of reportable results for two types of laboratory tests that already have a reporting requirement.

Private Laboratories and Hospitals

In the current language, laboratories are required to report the results of CD4 (T-helper lymphocyte) tests that meet the CDC definition for an AIDS case using CD4 levels. The Division's proposed change would require reporting for all CD4 results, regardless of level. In addition, the proposed change clarifies the reporting for viral load tests to include reporting of all results, including non-detectable viral loads. In the current version of the rule, laboratories were often unsure about reporting viral load results that were undetectable. The rule change does not add additional tests to those that laboratories are required to report; the Division is only proposing to expand the range of results that had been previously set. Both of these tests are routine for monitoring clinical progress for persons living with HIV.

We do not believe these changes will create any significant additional burden for those laboratories that are currently reporting CD4 and viral loads to the Division of Public Health (estimates of additional cost burdens calculated below and in Table 1 on page 6). The volume of reports will certainly increase, but in most laboratories these public health reporting activities are automated. This change will entail a minor modification of the test result limits the automated procedure utilizes to identify reportable results. Conversations with a major reference laboratory about the impact of changing the reporting limits have indicated that the impact of the proposed change is trivial. For laboratories without an automated reporting procedure, we anticipate that the process to select the range of reportable results will be similar to that used by laboratories using an automated process. The difference between these two approaches is that laboratories without automation require a user to initiate the batch reporting on a regular basis. For such facilities to comply, the limits for both the CD4 and viral loads must be modified. Currently, we have four laboratories that will fall into this category.

One commercial laboratory shared their reporting volume for all CD4 results. Based on our experience with the number of reports we receive under the current reporting requirements and the testing volume provided, we anticipate an increase of at least 100% in volume when this particular laboratory begins reporting all CD4 levels. This laboratory is still providing hardcopy reports via automated fax or secure email reports to our office. Despite the increase in reporting volume, the laboratory has indicated to the Division that the impact on the current submission will be negligible from the laboratory's side.

There are four additional commercial laboratories that provide both CD4 and viral load results via mailed reports, but at a much lower volume than the laboratory described above. Our expectation is that the additional postage resulting from increased reporting will be on the order of an additional \$1 or less per week for these laboratories. We are in negotiations with these laboratories to begin reporting via ELR to our NCEDSS system as soon as possible. At the time when ELR feeds are established the issue of hardcopy reporting and the associated postage will no longer be applicable. Given the projections described for viral load results, we anticipate the same relative increase in volume at the point they submit all CD4 results. We already receive a significant number of viral load reports where the reported result is an undetected viral load, leading us to believe that the proportionate increase in viral load reporting will be far less than for reporting all CD4 results. Based on professional judgment, the experience of other states implementing such a change in laboratory reporting, and preliminary data from a commercial laboratory, we have estimated that viral load reporting may increase by as much as 50% when all commercial and hospital laboratories fully implement full viral load reporting. (These data as well as other information are represented in Table 1 on page 6.)

In addition to the five commercial laboratories mentioned, four hospital systems also perform CD4 and viral load testing. One of those hospitals is currently sending an electronic laboratory report (ELR) to our NC Electronic Disease Surveillance System (NCEDSS) system and will be immediately able to begin sending CD4 and viral load results via ELR at the time we implement HIV reporting in NCEDSS. Again, we anticipate that we will have NCEDSS able to receive HIV reports before the implementation of this rule. The other three hospital systems are providing test results via a mix of mailed paper and encrypted file transfers.

We have estimated a maximum potential impact on laboratories from the perspective in changes necessary to modify a laboratory's information management system (LIMS). We estimated a maximum of 40 hours of time to modify the LIMS code and test the change to select all results for CD4 and viral load tests performed (each). Based on comparable positions in DPH for IT specialists and wage data for computer programmers at medical laboratories from the Bureau of Labor Statistics, the Division assumed an hourly compensation estimate of \$48 for the opportunity cost of a specialist's time. As reported in Table 1, the resulting estimate for total costs associated with modifying and testing LIMS code is \$1,920 for each change to testing output (\$3,840 for viral load and CD4). This value was then multiplied by 9, representing the laboratories from which we receive viral load and CD4 results (total cost of approximately \$35,000). This is, in our opinion, a high-end estimate for the time and impact likely to actually occur. Depending on the LIMS, these changes can be implemented with only a few hours of time required to make the output code change.

State Impact

The proposed change will introduce an additional burden on staff in the CD Branch who perform laboratory data entry into our surveillance databases. However, we anticipate that at the time this rule is implemented, our NCEDSS will be fully implemented and with that implementation the ability for the system to receive an electronic laboratory report from laboratories will be in place. The ELR provides an automated matching of incoming laboratory report information with existing disease reports and attaches laboratory results to the existing disease report using an automated process. Manual data entry is not required using this process. While there will be some additional manual data entry burden for reports from laboratories that do not have the capability to provide ELR feeds immediately, which will generate opportunity costs of staff time, we anticipate this burden will be of a magnitude that can be handled with existing staffing in the Communicable Disease Surveillance Unit (CDSU).

Upon the addition of HIV/syphilis reporting to our NCEDSS, the primary function of the CDSU registrars will shift from all data entry to a combination of data entry and data validation. Because of the ELR import rules we have in place, much of the routine data entry will be automated through the ELR. Staff will be responsible for monitoring data quality in the new electronic reporting system. Our current business process is that all laboratory reports for HIV-related testing is reported to the Surveillance Unit via some sort of manual process (mailed, faxed or emailed report) and those reports are manually entered into the HIV surveillance database. The current load for data entry on an annual basis is approximately 53,000 laboratory reports processed and entered. Currently one commercial laboratory provides approximately 65% of the laboratory reports coming to the Surveillance Unit. That particular laboratory is one that already has an ELR feed in place so there will be a loss of manual laboratory report entry as we implement our NCEDSS for HIV reporting. The additional burden of manual laboratory reports from other laboratories not yet providing an ELR feed is anticipated to be of similar volume to the amount of reporting provided by ELR, but because of the smaller "footprint" of the laboratories providing hard copy reports the overall impact will be relatively small. Table 1 on page 6 provides estimates of the additional data entry costs. Based on an approximation of 0.1 hours for manual search and data entry, we estimate that the increase in viral load and CD4 report manual data entry will cost approximately \$4,800 in staff time.

Benefits

Successful management of HIV infection should result in a person's CD4 counts remaining in a near normal range (relative to a non-infected person) while also having a non-detectable HIV viral load. When patients are virally suppressed, their likelihood of transmitting HIV is dramatically decreased to the point that they are essentially non-infectious. In the absence of a cure for HIV, rendering a person who is infected with the virus incapable of transmitting the virus to a partner is likely to result in substantial, but hard-to-quantify, benefits to public health. Ongoing assessment of HIV viral loads and CD4 tests therefore enable a mechanism to possibly indicate whether a client has received regular HIV care visits and to document the results of such visits.

In addition to the direct benefit to our ongoing evaluation of HIV care delivery and our assessment of viral suppression, implementation of this rule change ensures there is no impediment to North Carolina continuing to receive federal funding for HIV/AIDS prevention, surveillance or care activities from our myriad of federal partners.

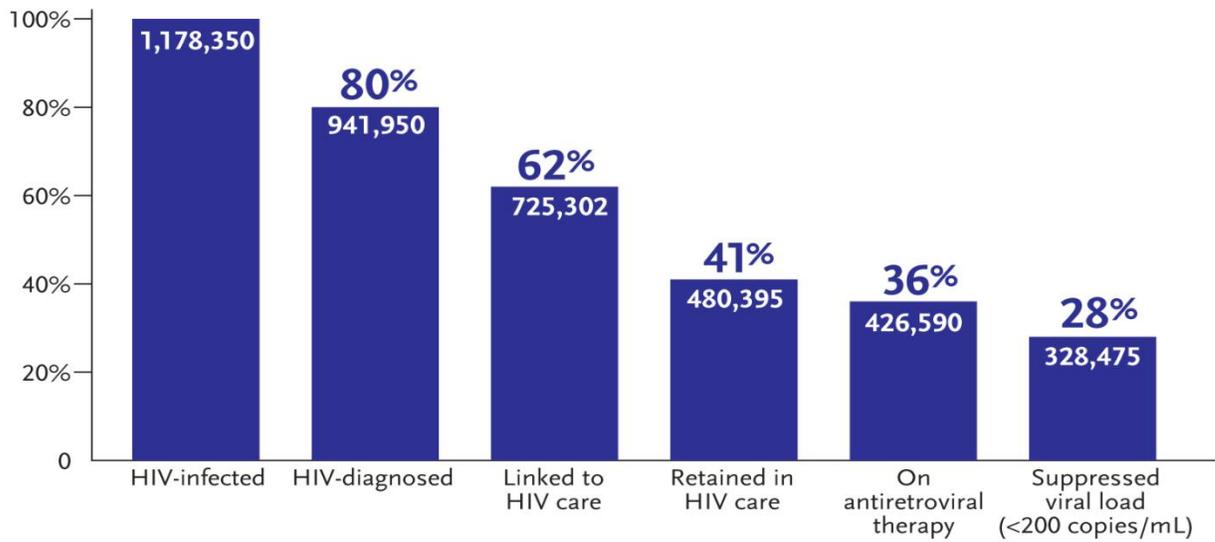
Table 1: NC DPH Laboratory Reporting of All Viral Load and CD4 Results				
Impact Analysis				
Projected Impact based on 2011 Reports				
Baseline (Based on 2011 Lab Reports Received)				
Type of Lab	2011 Reports (approximate)	Projected Reports (annual)		
Viral Load	32,400	57,000		
CD4	21,500	43,000		
Impact on Laboratories: IT Services to Modify Reporting Criteria in the Laboratory Information System (Estimated)				
Type of Lab	Total Hours per Lab Parameter Changed	Hourly Salary of IT Specialist	Total Cost to Agency	
Viral Load	40	\$48.00	\$1,920	
CD4	40	\$48.00	\$1,920	
Total/Laboratory	80		\$3,840	
Total Impact for 9 Affected Laboratories (one-time)			\$35,000 (rounded)	
Impact on Communicable Disease Surveillance Unit: Changes in effort as a result of the proposed change (Estimated)				
Lab Test Reported	Current Reports	Projected Reports	Manual Entry Projected*	Estimated Cost**
Western Blot	2,800	2,800	1,500	\$267
Viral Load	32,400	57,000	17,000	\$3,112
CD4	21,500	43,000	8,200	\$1,458
State Impact (recurring)				\$5,000 (rounded)

*With NCEDSS implemented, staff responsibilities change from data entry to data validation activities

** Estimated costs are based on the presumption that each record will require 0.1 hr of data entry time by a staff member who earns \$37,000 per year on average (or 17.78/hour). As additional laboratories enable electronic laboratory reporting to the Division of Public Health, the manual data entry effort will decline.

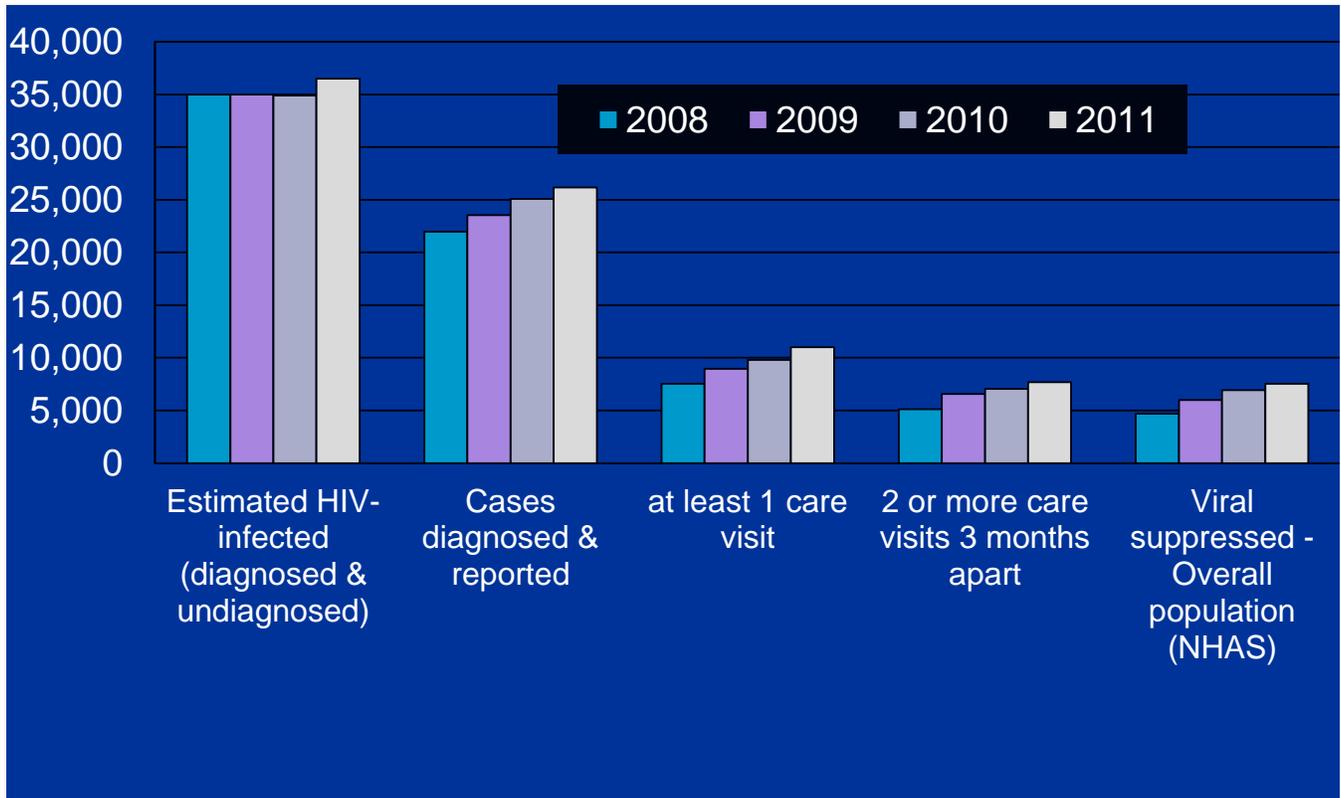
In conclusion, the Division does not believe these changes will create a significant additional burden for those laboratories who are currently reporting CD4 and viral loads to the Division of Public Health. The volume of reports will certainly increase, but in most laboratories these public health reporting activities are automated. This change will entail a minor modification of the test result limits the automated procedure utilizes to identify reportable results. The Division also does not anticipate the increase in reports to result in a need for additional staff resources to enter information into the surveillance system because the change will occur as the Division moves toward increasing reliance on electronic laboratory reporting.

Proportion of HIV-positive Individuals in the U.S. at Each Stage of Care



Source: CDC

NC HIV Cascade, overall population Diagnosed 2007-2010 and living through 2008-2011



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

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) anthrax - immediately;
- (3) botulism - immediately;
- (4) brucellosis - 7 days;
- (5) campylobacter infection - 24 hours;
- (6) chancroid - 24 hours;
- (7) chlamydial infection (laboratory confirmed) - 7 days;
- (8) cholera - 24 hours;
- (9) Creutzfeldt-Jakob disease – 7 days;
- (10) cryptosporidiosis - 24 hours;
- (11) cyclosporiasis - 24 hours;
- (12) dengue - 7 days;
- (13) diphtheria - 24 hours;
- (14) Escherichia coli, shiga toxin-producing - 24 hours;
- (15) ehrlichiosis - 7 days;
- (16) encephalitis, arboviral - 7 days;
- (17) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes - 24 hours;
- (18) gonorrhea - 24 hours;
- (19) granuloma inguinale - 24 hours;
- (20) Haemophilus influenzae, invasive disease - 24 hours;
- (21) Hantavirus infection – 7 days;
- (22) Hemolytic-uremic syndrome – 24 hours;
- (23) Hemorrhagic fever virus infection –immediately;
- (24) hepatitis A - 24 hours;
- (25) hepatitis B - 24 hours;
- (26) hepatitis B carriage - 7 days;
- (27) hepatitis C, acute - 7 days;
- (28) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
- (29) influenza virus infection causing death in persons less than 18 years of age – 24 hours;
- (30) legionellosis - 7 days;
- (31) leprosy – 7 days;
- (32) leptospirosis - 7 days;
- (33) listeriosis – 24 hours;

- (34) Lyme disease - 7 days;
- (35) lymphogranuloma venereum - 7 days;
- (36) malaria - 7 days;
- (37) measles (rubeola) - 24 hours;
- (38) meningitis, pneumococcal - 7 days;
- (39) meningococcal disease - 24 hours;
- (40) monkeypox – 24 hours;
- (41) mumps - 7 days;
- (42) nongonococcal urethritis - 7 days;
- (43) novel influenza virus infection – immediately;
- (44) plague - immediately;
- (45) paralytic poliomyelitis - 24 hours;
- (46) pelvic inflammatory disease – 7 days;
- (47) psittacosis - 7 days;
- (48) Q fever - 7 days;
- (49) rabies, human - 24 hours;
- (50) Rocky Mountain spotted fever - 7 days;
- (51) rubella - 24 hours;
- (52) rubella congenital syndrome - 7 days;
- (53) salmonellosis - 24 hours;
- (54) severe acute respiratory syndrome (SARS) – 24 hours;
- (55) shigellosis - 24 hours;
- (56) smallpox –immediately;
- (57) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
- (58) streptococcal infection, Group A, invasive disease - 7 days;
- (59) syphilis - 24 hours;
- (60) tetanus - 7 days;
- (61) toxic shock syndrome - 7 days;
- (62) trichinosis - 7 days;
- (63) tuberculosis - 24 hours;
- (64) tularemia - immediately;
- (65) typhoid - 24 hours;
- (66) typhoid carriage (Salmonella typhi) - 7 days;
- (67) typhus, epidemic (louse-borne) - 7 days;
- (68) vaccinia – 24 hours;
- (69) vibrio infection (other than cholera) - 24 hours;
- (70) whooping cough - 24 hours;
- (71) yellow fever - 7 days.

(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:

- (1) Isolation or other specific identification of the following organisms or their products from human clinical specimens:
 - (A) Any hantavirus or hemorrhagic fever virus.
 - (B) Arthropod-borne virus (any type).
 - (C) *Bacillus anthracis*, the cause of anthrax.
 - (D) *Bordetella pertussis*, the cause of whooping cough (pertussis).
 - (E) *Borrelia burgdorferi*, the cause of Lyme disease (confirmed tests).
 - (F) *Brucella* spp., the causes of brucellosis.
 - (G) *Campylobacter* spp., the causes of campylobacteriosis.
 - (H) *Chlamydia trachomatis*, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
 - (I) *Clostridium botulinum*, a cause of botulism.
 - (J) *Clostridium tetani*, the cause of tetanus.
 - (K) *Corynebacterium diphtheriae*, the cause of diphtheria.
 - (L) *Coxiella burnetii*, the cause of Q fever.
 - (M) *Cryptosporidium parvum*, the cause of human cryptosporidiosis.
 - (N) *Cyclospora cayentanesis*, the cause of cyclosporiasis.
 - (O) *Ehrlichia* spp., the causes of ehrlichiosis.
 - (P) Shiga toxin-producing *Escherichia coli*, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
 - (Q) *Francisella tularensis*, the cause of tularemia.
 - (R) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
 - (S) Human Immunodeficiency Virus, the cause of AIDS.
 - (T) *Legionella* spp., the causes of legionellosis.
 - (U) *Leptospira* spp., the causes of leptospirosis.
 - (V) *Listeria monocytogenes*, the cause of listeriosis.
 - (W) Monkeypox.
 - (X) *Mycobacterium leprae*, the cause of leprosy.
 - (Y) *Plasmodium falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*, the causes of malaria in humans.

- (Z) Poliovirus (any), the cause of poliomyelitis.
 - (AA) Rabies virus.
 - (BB) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
 - (CC) Rubella virus.
 - (DD) *Salmonella* spp., the causes of salmonellosis.
 - (EE) *Shigella* spp., the causes of shigellosis.
 - (FF) Smallpox virus, the cause of smallpox.
 - (GG) *Staphylococcus aureus* with reduced susceptibility to vanomycin.
 - (HH) *Trichinella spiralis*, the cause of trichinosis.
 - (II) Vaccinia virus.
 - (JJ) *Vibrio* spp., the causes of cholera and other vibrioses.
 - (KK) Yellow fever virus.
 - (LL) *Yersinia pestis*, the cause of plague.
- (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 viruses associated with meningitis or encephalitis in a human.
 - (ii) Any hantavirus or hemorrhagic fever virus.
 - (iii) *Chlamydia psittaci*, the cause of psittacosis.
 - (iv) *Coxiella burnetii*, the cause of Q fever.
 - (v) Dengue virus.
 - (vi) *Ehrlichia* spp., the causes of ehrlichiosis.
 - (vii) Measles (rubeola) virus.
 - (viii) Mumps virus.
 - (ix) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
 - (x) Rubella virus.
 - (xi) Yellow fever virus.
 - (B) The presence of IgM serum antibodies to:
 - (i) *Chlamydia psittaci*
 - (ii) Hepatitis A virus.
 - (iii) Hepatitis B virus core antigen.
 - (iv) Rubella virus.
 - (v) Rubeola (measles) virus.
 - (vi) Yellow fever virus.

- (4) Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4) subset of lymphocytes ~~that have a level below that specified by the Centers for Disease Control and Prevention as the criteria used to define an AIDS diagnosis~~ and all results from tests to determine HIV viral load including a result reported as undetectable.

History Note: Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141