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MEMORANDUM

TO: Directors of Medical Laboratories

FROM: HIV/AIDS Surveillance Program, Nevada Division of Public and Behavioral Health

RE: Changes in Nevada Administrative Code (NAC 441A.235)

Effective September 2015, important changes in regulations pertaining to the reporting by laboratories of results related to human immunodeficiency virus (HIV) infection were implemented by the Nevada State Board of Health. These changes expand the laboratory results to be reported to include certain tests for the human immunodeficiency virus (HIV) or its antibodies.

According to the revisions (see NAC 441.235.5), the director or other person in charge of a medical laboratory shall report the results of any test of any specimen derived from the human body to the health authority if:

- The test results confirm the presence of HIV; or
- The test was conducted to monitor the progression of HIV, <u>including</u>, <u>without limitation</u>, all levels of CD4, and both detectable and undetectable viral loads.

If the interpretation of the laboratory diagnostic testing algorithm is positive for HIV, the laboratory must report to the health authority:

- The overall result or conclusion of the algorithm; and
- Results from all such tests, including negative, nonreactive, or intermediate results.

To view these changes, go to: https://www.leg.state.nv.us/NAC/NAC-441A.html or see attachment 1 for changes to 441.235. See http://dpbh.nv.gov/Programs/HIV-OPHIE/dta/Providers/HIV/AIDS - Providers/Providers/HIV/AIDS - Providers/Providers/HIV/AIDS - Providers/Providers/HIV/AIDS - Providers/Providers/HIV/AIDS - Providers/Providers/HIV/AIDS - Providers/HIV/AIDS - <a href="https

Attachment 1

NAC 441.235

EXPLANATION - Matter in italics is new; matter in brackets [omitted material] is material to be omitted.

- **Sec. 5.** NAC 441A.235 is hereby amended to read as follows:
- 441A.235 1. Except as otherwise provided in NAC 441A.240, the director or other person in charge of a medical laboratory in which a test or examination of any specimen derived from the human body yields evidence suggesting the presence of a communicable disease, a causative agent of a communicable disease or an immune response to a causative agent of a communicable disease shall:
- (a) If the medical laboratory is in this State, report the findings to the health authority having jurisdiction where the office of the health care provider who ordered the test or examination is located or to an electronic clearinghouse approved by the health authority.
- (b) If the medical laboratory performed the test or examination on specimens obtained in this State or from residents of this State, and the medical laboratory is located outside of this State, report the findings to the [State Health] Chief Medical Officer.
- → The report must be made in the manner provided in NAC 441A.225.
 - 2. The report must include:
 - (a) The date and result of the test or examination performed.
- (b) The name, address and, if available, telephone number of the person from whom the specimen was obtained.
- (c) The *sex*, age [or] *and* date of birth of the person from whom the specimen was obtained, if available.
 - (d) The name of the health care provider who ordered the test or examination.

- (e) The name and the address or telephone number of the medical laboratory making the report.
 - (f) Any other information requested by the health authority, if available.
- 3. The director or other person in charge of the medical laboratory shall also submit microbiologic cultures, subcultures, or other specimens or clinical material, if available, to the State Public Health Laboratory or other laboratory designated by the health authority for diagnosis, confirmation or further testing if:
 - (a) Requested by the health authority;
- (b) The communicable disease is included on the list of diseases published by the health authority pursuant to subsection 4 and the health authority has provided the director or other person in charge of the medical laboratory with a copy of the list; or
 - (c) The microbiologic cultures, subcultures, or other specimens or clinical material consist of:
 - (1) Isolates of Bordetella pertussis or Bordetella parapertussis;
 - (2) Isolates of non-motile and non-hemolytic *Bacillus* spp.;
 - (3) Isolates of *Brucella* spp.;
 - (4) Isolates of Burkholderia mallei or Burkholderia pseudomallei;
 - (5) Isolates of *Campylobacter* spp.;
 - (6) Isolates of *Clostridium botulinum*;
 - (7) Isolates of *Clostridium tetani*;
 - (8) Isolates of Corynebacterium diptheriae;
 - (9) Isolates of Coxiella burnetii;
 - (10) Isolates of *E. coli* O157:H7;

- (11) Isolates of Francisella tularensis;
- (12) Isolates of *Haemophilus influenza* (invasive only);
- (13) Isolates of Legionella spp.;
- (14) Isolates of Listeria monocytogenes;
- (15) Isolates of Mycobacterium spp.;
- (16) Isolates of *Neisseria meningitidis* from a sterile site;
- (17) Blood smears containing *Plasmodium* spp.;
- (18) Isolates of Salmonella spp.;
- (19) Isolates of, or broth positive results for, Shiga-toxin producing E. coli;
- (20) Isolates of Shigella spp.;
- (21) Isolates of *Vibrio* spp.;
- (22) Isolates of Vancomycin-intermediate Staphylococcus aureus;
- (23) Isolates of Vancomycin-resistant Staphylococcus aureus;
- (24) Isolates of Yersinia pestis; or
- (25) Isolates of Yersinia spp., other than Yersinia pestis.
- 4. The health authority shall annually publish and post on its Internet website a list of communicable diseases for which microbiologic cultures, subcultures, or other specimens or clinical material, if available, must be submitted pursuant to subsection 3. For each communicable disease included on the list, the health authority must specify:
- (a) The microbiologic cultures, subcultures, or other specimens or clinical material to be submitted;

- (b) The justification for requiring the microbiologic cultures, subcultures, or other specimens or clinical material to be submitted;
- (c) The name of the medical laboratory to which the microbiologic cultures, subcultures, or other specimens or clinical material must be submitted; and
- (d) The process by which the microbiologic cultures, subcultures, or other specimens or clinical material must be submitted.
- 5. [A test or examination that is performed by a medical laboratory and reveals CD4 lymphocyte counts of less than 500 cells per microliter constitutes evidence suggesting the presence of a communicable disease and must be reported] Except as otherwise provided in NAC 441A.240, the director or other person in charge of a medical laboratory shall report as required by this section [.] the results of any test of any specimen derived from the human body, if the test is approved by the Food and Drug Administration of the United States Department of Health and Human Services, and:
- (a) The results of the test confirm the presence of the human immunodeficiency virus (HIV) or antibodies to the human immunodeficiency virus (HIV); or
- (b) The test was conducted to monitor the progression of a human immunodeficiency virus (HIV) infection, including, without limitation, all levels of CD4, and both detectable and undetectable viral loads.
- 6. With respect to a test described in subsection 5, if the interpretation of the laboratory diagnostic testing algorithm is positive, indicating the presence of infection with the human immunodeficiency virus (HIV), the laboratory must report to the health authority:
 - (a) The overall result or conclusion of the algorithm; and

- (b) Results from all such tests, including, without limitation, negative, nonreactive or intermediate results, that are performed as part of the testing algorithm, including, without limitation:
- (1) Fourth-generation and third-generation tests for the human immunodeficiency virus (HIV);
 - (2) Human immunodeficiency virus antibody differentiation tests (HIV-1/-2); and
- (3) Nucleic acid amplification tests (NAT) for the presence of the human immunodeficiency virus (HIV).