

/* MISSOURI administrative regulations from their Department of Health deal with tests, consultation and reporting performed by the Department and by private physicians. */

Title 19-DEPARTMENT OF HEALTH

Division 20-Division of Environmental Health and Epidemiology

Chapter 26-Sexually Transmitted Diseases

19 CSR 20-26.030 Human Immunodeficiency Virus (HIV) Antibody Test Consultation and Reporting

PURPOSE: This rule defines the manner in which the sampling and consultation for human immunodeficiency virus antibody testing is to be administered by persons authorized by the Department of Health and the reporting of positive test results.

(1) The following definitions shall be used in administering this rule:

- (A) Department means the Missouri Department of Health;
- (B) Health care professional means a state licensed professional involved in direct patient care, other than those persons licensed as physicians under Chapter 334, RSMo; and
- (C) Window period means the interval between exposure to human immunodeficiency virus (HIV) and development of a positive antibody test.

(2) To be authorized by the department to do HIV sampling, a person shall be a health care professional or able to provide accurate and current information about HIV serologic testing along with pretest and posttest consultation in accordance with this rule and shall provide or make provisions for pretest and posttest consultation in person to the person tested or his/her legal guardian or custodian. If after investigation by a department employee, the person responsible for sampling is determined not to be observing the provisions of this rule, the department shall deny authorization.

(A) Pretest consultation shall occur before sampling and include a risk assessment of the person to be tested to determine the person's potential for exposure and infection. The person to be tested shall be advised of the etiology and methods of transmission of HIV, the testing methodology, the meaning of the test results and the type of behavior necessary to reduce the risk of exposure to the virus.

(B) Posttest consultation shall also be provided to all persons tested for HIV anti-bodies. It shall include the test results and their significance,

information on good preventive and risk reduction practices and referral of the person for medical care and other support services as needed. If the test results are negative, the person tested shall be advised of the window period and possible need for retesting. If the test results are equivocal, the person shall also be advised of the possible need for retesting.

(C) If the test results are positive, the identity of the person tested along with related clinical and identifying information shall be reported to the department or its designated representative by the person who performs or conducts HIV sampling within seven (7) days of receipt of the test results on forms provided by the Department of Health (see Form #1).

(D) Sites testing persons under the following situations shall be exempt from reporting the identity of persons testing positive for HIV. These sites shall report HIV positive test results as well as other related clinical and identifying information within seven (7) days of receipt of the test results on forms provided by the Department of Health (see Form #1), but shall be exempt from reporting the patient's name and street address-instead a unique patient identifier shall be used:

1. Persons tested at department-designated anonymous testing sites;
2. Persons tested as part of a research project approved by an institutional review board with notification of the board's approval submitted to the department in writing; or
3. Where prohibited by federal law or regulation;

(E) Laboratories which perform testing shall report identifying information as specified in 19 CSR 20-20.080; and

(F) All persons reported to the department with HIV infection to the department or its designated representative shall be treated as referrals for public health partner elicitation/notification services according to protocols and procedures established by the department.

19 CSR 20-26.040 Physician Human Immunodeficiency Virus (HIV) Antibody Test Consultation and Reporting

PURPOSE: This rule establishes guide-lines specific to physicians and other health care professionals working under physician orders for human immunodeficiency virus blood sampling and pretest and posttest consultation and for the reporting of persons diagnosed with human immunodeficiency virus infection.

(1) The following definitions shall be used in administering this rule:

- (A) Conduct means to direct, lead, order or undertake to perform or to provide guidance as a licensed physician to a patient;
- (B) Confirmed human immunodeficiency virus (HIV) infection means the clinical diagnosis and conclusion that a patient is infected with HIV, made in the professional judgment of the physician based upon clinical history, physician examination, diagnostic or laboratory serological testing or other available clinical information which allows the physician to make clinical and therapeutic decisions based upon this infected status;
- (C) Department means the Missouri Department of Health;
- (D) Physician means any person licensed to practice as a physician and surgeon under Chapter 334, RSMo;
- (E) Physician's delegated representative means state licensed professional involved in direct patient care, other than those persons licensed as physicians under Chapter 334, RSMo; and
- (F) Serological test means-
1. A serum specimen repeatedly reactive for HIV antibody by a licensed screening test (for example, enzyme-linked immunosorbent assay (ELISA)) that has been verified by a more specific subsequent test (such as Western Blot or immunofluorescence assay (IFA));
 2. A positive lymphocyte culture verified by a specific HIV antigen test or by in situ hybridization using a deoxyribonucleic acid (DNA) probe;
 3. A positive result on any other highly specific test for HIV; or
 4. A T-Helper (CD4) lymphocyte count performed as a part of the clinical management of a person who in the professional judgment of the physician is infected with HIV.
- (2) The physician or the physician's delegated representative shall provide consultation with the patient or his/her legal guardian or custodian prior to conducting HIV blood sampling, and to the patient, guardian or custodian during the reporting of the test results or diagnosis.
- (A) The physician or the physician's delegated representative shall only be allowed to provide consultation through the use of protocols and standing orders which shall be written, signed and dated by the physician prior to their implementation or, in the case of a hospital, the policies and procedures as approved by the medical staff.
- (B) The scope of the consultation shall be governed by the physician's professional judgment based on the clinical situation, including the purpose of and need for HIV testing, and shall be at least as comprehensive as the

type of consultation provided for other diagnostic tests or procedures.

(3) The physician shall report to the department or its designated representative the identity of any person with confirmed HIV infection along with related clinical and identifying information within seven (7) days of receipt of the test results on forms provided by the department (see Form #1 following 19 CSR 20-26.030).

(4) Physicians testing persons under the following situations shall be exempt from reporting the identity of the person testing positive for HIV. In these situations, physicians shall report HIV positive test results as well as other related clinical and identifying information within seven (7) days of receipt of the test results on forms provided by the department (see Form #1 following 19 CSR 20-26.030), but shall be exempt from reporting the patient's name and street address-instead a unique patient identifier shall be used.

(A) Persons tested solely as part of a research project at those sites participating in a research project approved by an institutional review board with notification of the board's approval submitted to the department in writing; or

(B) Where prohibited by federal law or regulation.

(5) All persons reported with HIV infection to the department or its designated representative shall be treated as referrals for public health partner elicitation/notification services according to protocols and procedures established by the department.