Rules of
Department of Health
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Chapter 33—Laboratories for Serologic Tests for Human Immunodeficiency Virus Antibodies

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Title 19—DEPARTMENT OF HEALTH

Division 25—Division of Administration

Chapter 33—Laboratories for Serologic Tests for Human Immunodeficiency Virus Antibodies

19 CSR 25-33.010 Approval of Laboratories for the Performance of Serologic Tests for Human Immunodeficiency Virus Antibodies in Blood

PURPOSE: This rule establishes the procedures and requirements for laboratories performing serologic tests on serum or plasma for detection of antibodies to Human Immunodeficiency Virus in order to be approved to conduct HIV tests by the Department of Health.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) The director of a laboratory seeking Department of Health (DOH) approval to perform serologic tests for detection of the Human Immunodeficiency Virus (HIV) antibodies shall make written application to the director, State Public Health Laboratory, DOH.

(A) Hospitals licensed according to Chapter 197, RSMo shall be considered to be in compliance with departmental rules governing serologic tests for detection of HIV antibodies.

(B) In addition to applying for approval, the laboratory shall be in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). A copy of the currently valid CLIA certificate shall be initially submitted to the director, State Public Laboratory, DOH to obtain DOH approval. When CLIA certificates are renewed, a copy must be submitted to the director, State Public Health Laboratory, DOH for renewal of DOH approval certificate.

(C) Serologic tests to be used for detection of antibody to the HIV virus are—Enzyme Immunoassay (EIA), Immunoblot (Western Blot) and Indirect Immunofluorescence (IFA).

(D) All laboratory testing shall be conducted at the address given when application for approval is made. Written notice of change of address shall be given to DOH prior to actually moving the testing facilities.

(2) DOH shall issue a certificate of approval to a laboratory meeting the requirements of this rule. The certificate is effective until revoked and will be renewed upon receipt of a copy of updated CLIA certification and applies only to the laboratory to which it is issued.

(3) A certificate of approval may be revoked when a participating laboratory discontinues its testing services or fails to meet the requirements of CLIA 88 which relate to serologic testing for antibodies to HIV.

AUTHORITY: sections 191.653, RSMo (Supp. 1988) and 192.005.2, RSMo (1986). This rule was previously filed as 19 CSR 20-33.010. Original rule filed Jan. 19, 1989, effective April 13, 1989. Rescinded and readopted: Filed Jan. 15, 1993, effective July 8, 1993. Changed to 19 CSR 25-33.010 Jan. 1, 1995.*

**Original authority 191.653, RSMo (1988) and 192.005.2, RSMo (1985).*