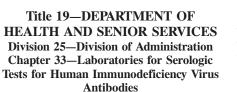
Rules of Department of Health and Senior Services

Division 25—Division of Administration Chapter 33—Laboratories for Serologic Tests for Human Immunodeficiency Virus Antibodies

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

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 secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) The director of a laboratory seeking Department of Health and Senior Services (DHSS) approval to perform serologic tests for detection of the Human Immunodeficiency Virus (HIV) antibodies shall make written application on form Lab 125, which is incorporated by reference, to the director, State Public Health Laboratory, DHSS.

(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 Health Laboratory, DHSS to obtain DHSS approval.

(C) All laboratory testing shall be conducted at the address given when application for the approval is made. Written notice of change of address shall be given to DHSS prior to actually moving the testing facilities. (2) DHSS shall issue a certificate of approval to a laboratory meeting the requirements of this rule. The certificate is effective until revoked.

(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. Compliance will be monitored by Department of Health and Senior Services, Bureau of Health Facility Regulation, CLIA program.

AUTHORITY: sections 191.653 and 192.006, RSMo 2000.* 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. Amended: Filed Nov. 3, 2003, effective April 30, 2004.

*Original authority: 191.653, RSMo 1988, amended 1996; 192.006, RSMo 1993, amended 1995.