



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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**Title 19—DEPARTMENT OF
HEALTH AND SENIOR SERVICES
Division 25—Division of Administration
Chapter 33—Laboratories for Serologic
Tests for Human Immunodeficiency Virus
Antibodies**

**19 CSR 25-33.010 Approval of Laborato-
ries for the Performance of Serologic Tests
for Human Immunodeficiency Virus Anti-
bodies**

*PURPOSE: This rule establishes the proce-
dures and requirements for laboratories per-
forming serologic tests on serum or plasma
for detection of antibodies to Human Immun-
odeficiency 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 incorpo-
rated by reference as a portion of this rule
would be unduly cumbersome or expensive.
Therefore, the material which is so incorpo-
rated 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 refer-
ence 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.*