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**Rules of**  
**Department of Health and**  
**Senior Services**  
**Division 25—Division of Administration**  
**Chapter 34—Laboratories for Serologic Tests**  
**for Syphilis**

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**Title 19—DEPARTMENT OF  
HEALTH AND SENIOR SERVICES  
Division 25—Division of Administration  
Chapter 34—Laboratories for Serologic  
Tests for Syphilis**

**19 CSR 25-34.010 Approval of Laborato-  
ries for the Performance of Serologic Tests  
for Syphilis on Prenatal Blood**

*PURPOSE:* This rule deletes the requirement that test procedures for syphilis must be from the manual of tests for syphilis and allows for serologic testing by any method approved by the federal Food & Drug Administration (FDA) through compliance with CLIA 88 regulations.

*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 syphilis on prenatal blood specimens shall make written application on form Lab 126, which is incorporated by reference, to the director, State Public Health Laboratory, DHSS.

(A) 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.

(B) 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 the 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) The Certificate of Approval may be revoked when a participating laboratory dis-

continues its testing services or fails to meet the requirements of CLIA 88 which relate to syphilis serology. Compliance with CLIA 88 will be monitored by DHSS Bureau of Health Facility Regulation, CLIA program.

*AUTHORITY:* sections 192.006 and 210.030, RSMo 2000. \* This rule was previously filed as 13 CSR 50-142.010 and 19 CSR 20-34.010. Original rule filed Dec. 2, 1954, effective Jan. 1, 1955. Rescinded and readopted: Filed Dec. 7, 1981, effective April 11, 1982. Rescinded and readopted: Filed Jan. 15, 1993, effective July 8, 1993. Changed to 19 CSR 25-34.010 Jan. 1, 1995. Rescinded and readopted: Filed Nov. 3, 2003, effective April 30, 2004.

\*Original authority: 192.006, RSMo 1993, amended 1995; 210.030, RSMo 1941, amended 1986, 1993, 1998, 2000.