# Rules of
# Department of Health
## Division 25—Division of Administration
## Chapter 34—Laboratories for Serologic Tests for Syphilis

## Title 19—DEPARTMENT OF HEALTH
### Division 25—Division of Administration
### Chapter 34—Laboratories for Serologic Tests for Syphilis

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

*PURPOSE: State law requires that laboratories which perform serologic tests for syphilis for prenatal purposes must be approved by the Department of Health. This rule establishes the procedures and sets forth the requirements for laboratory approval.*

*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) Procedures for approval of laboratories to perform serologic tests for syphilis on prenatal blood specimens are—

(A) Application for evaluation and approval shall be made by the director of the applying laboratory to the director, State Public Health Laboratory, Department of Health (DOH);

(B) In order for a laboratory to be approved by DOH to perform serologic tests for syphilis, a copy of the current valid registration certificate showing compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) shall be submitted to the director, State Public Health Laboratory, DOH prior to the laboratory being approved by DOH;

(C) Tests are to be performed and reported in accordance with the standard procedures given in the 8th (1990) edition of the *Manual of Tests for Syphilis* of the United States Department of Health and Human Services; and

(D) A laboratory satisfactorily meeting the requirements of this rule will be issued a Certificate of Approval.

(2) The Certificate of Approval issued to a laboratory may be revoked when the approved laboratory discontinues its testing services or fails to meet the requirements of CLIA 88 which relate to syphilis serology.

*AUTHORITY: sections 192.005.2 and 210.030, RSMo (1986).* 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 Rescinded and readopted: Filed Dec. 7, 1981, effective April 11, 1982.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.*

**Original authority 192.005.2., RSMo (1985) and 210.030, RSMo (1941), amended 1986.*