

WEST VIRGINIA DEPARTMENT OF HEALTH
PROMULGATION HISTORY ABSTRACT

TITLE: Approval of Laboratories for Syphilis Serology, 16-1, Series VIII,
(1983)

RULE TYPE: Legislative

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Passed March 9, 1983; Effective from passage

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EFFECTIVE DATE: May 9, 1983

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE

THIS DATE 4/8/83
Administrative Law Division



L. Clark Hansbarger, M.D.
Director of Health

Entered

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Approval Of Laboratories For Syphilis Serology

Chapter 16-1
Series VIII
(1983)

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Chapter 16-1
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WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-1
Series 8
(1983)

Subject: Approval of Laboratories for Syphilis Serology

Section 1. General

1.1. Scope - These legislative rules establish the method of testing and approving laboratories for syphilis serology by the West Virginia department of health.

1.2. Authority - These legislative rules are issued under the authority of Chapter 16, Article 1, Section 7, Subsection (6) and are related to Chapter 48, Article 1, Section 6a of the West Virginia Code of 1931, as amended.

1.3. Filing Date - These legislative rules were promulgated on the 17th day of November, 1981, and were filed on the 8th day of April, 1983, in the Secretary of State's office.

1.4. Effective Date - These legislative rules became effective on the 9th day of May, 1983.

Section 2. Supersession and Repeal of Former Regulations - These legislative rules supersede and repeal the West Virginia Board of Health Regulations Chapter 4, Article 2 "Approval of Laboratories in West Virginia for Syphilis Serology.

Section 3. Application and Enforcement

3.1. Application - These legislative rules apply to all laboratories seeking certification under Premarital, Prenatal or Barber/Beautician Laws for syphilis serology by the West Virginia department of health.

3.2. Enforcement - Enforcement of these legislative rules is vested with the director of the West Virginia department of health or his lawful designee.

Section 4. Laboratories Eligible for Approval by the West Virginia Department of Health

4.1. Reports of official laboratories of State, Territorial and District of Columbia Health Departments and those approved by State, Territorial and District of Columbia Health Departments shall be honored, and also reports of official laboratories of the United States Military Service and the Public Health Service.

4.2. Except for the aforementioned laboratories, a laboratory seeking approval shall:

4.2.1. be located in West Virginia;

4.2.2. show that it complies with Chapter 16-1, Series VII Reportable Diseases Regulations; and Chapter 16-1, Series VI Requirement for Laboratories to Report Positive or Reactive Serologic and Other Tests for Syphilis and Positive Laboratory Examinations for Neisseria Gonorrhoea to the West Virginia department of health;

4.2.3. complete director qualification, personnel qualification, and agreement forms when a laboratory requests approval for the first time or when there is a change in laboratory director;

4.2.4. maintain adequate apparatus and reagents for tests for which approval is requested;

4.2.5. send its request for approval to the West Virginia department of health well in advance of future yearly testing periods;

4.2.6. meet the accuracy standards of these regulations (Section 6).

Section 5. Proficiency Surveys and Duration of Certificates of Approval

5.1. A proficiency survey is defined as a series of specimens sent to a laboratory for the purpose of appraising the accuracy of its results.

5.2. The opening date of the annual proficiency survey shall be set by the West Virginia department of health; laboratories in West Virginia shall be notified in advance of the approximate opening date.

5.3. A Certificate of Approval shall be issued to a laboratory which satisfactorily completes the required proficiency survey in accordance with these regulations. The certificate shall be in effect to the end of the calendar year following the year in which the proficiency survey was completed.

5.4. Each certificate shall be issued to a specific laboratory for a specific period of time, and shall list the name of the tests approved. It shall bear the name and address of the laboratory to which it is issued and the name of its director. A certificate shall be void if there is a change in laboratory director, laboratory location or change in testing procedure or technique; or unethical practice as determined by the West Virginia board of health.

Section 6. Sensitivity and Specificity Standards for Approval

A Certificate of Approval shall be granted by the West Virginia department of health to a laboratory which in a proficiency survey demonstrates a reasonable approximation to American Standards on sensitivity and specificity with a standard serologic test for syphilis.

Section 7. Agreement of Laboratory for Approval of Serologic Tests for Syphilis

Laboratories in West Virginia seeking approval of serologic tests for syphilis shall submit an agreement form to the West Virginia department of health on forms supplied by the West Virginia department of health for that purpose.

Section 8. Administrative Due Process - Those persons adversely affected by the enforcement of these legislative rules desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the West Virginia Procedural Rules, Board of Health, Chapter 16-1, Series I, 1981, Rules of Procedures for Contested Case Hearings and Declaratory Rulings. The aforementioned procedural rules are incorporated herein by reference.

Section 9. Severability - If any provisions of these rules or the application thereof to any person or circumstance shall be held invalid, such invalidity thereof shall not affect the provisions or application of these rules which can be given effect without the invalid provisions or application, and to this end the provisions of these rules are declared to be severable.