

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Approval of Laboratories for Syphilis Serology

Chapter 16-1
Series VIII
(1983)

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for Syphilis Serology

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WEST VIRGINIA LEGISLATIVE RULE
BOARD OF HEALTH

Chapter 16-1
Series VIII
(1983)

Subject: Approval of Laboratories in West Virginia for Syphilis Serology

Section 1. General

1.1. Scope - These legislative rules establish the methods for testing and approving laboratories for syphilis serology.

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

1.3. Filing Date - These rules were filed on the 18th day of November 1964, in the Secretary of State's office.

1.4. Effective Date - These legislative rules became effective on the 19th day of December 1964.

1.5. Refiling Date - These legislative rules were refiled pursuant to Chapter 29A, Article 2, Section 5 of the West Virginia Code of 1931, as amended on the 30th day of December 1982, in the Secretary of State's office.

Section 2. Application and Enforcement

2.1. Application - These legislative rules apply to any laboratory seeking approval by the West Virginia department of health for syphilis serology.

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

Section 3. General Method - The method of testing and approving eligible applicants shall be the method adopted in 1939 by the West Virginia department of health. The purpose is to appraise proficiency of performance of a specified standard serologic test for syphilis.

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 shall be honored, and also reports of official laboratories of the United States Army, Navy, Marines, and Public Health Service.

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

1. be located in West Virginia;
2. show that it complies with 16-1 Series;
3. complete questionnaire and agreement forms (HL-C and HL-D); form HL-C annually, and form HL-D when a laboratory requests approval for the first time, or when there is change of direction.
4. maintain adequate apparatus and reagents for tests for which approval is requested;
5. send its request for approval to the West Virginia department of health well in advance of future yearly testing periods;
6. meet the accuracy standards of Section 6.

Section 5. Testing Periods And Duration Of Certificates Of Approval.

5.1. Testing of eligible laboratories applying for approval shall be carried out once annually by means of a proficiency survey; except that a

laboratory which employs two or more standard serological tests and which has obtained results in two consecutive annual proficiency surveys justifying the issuance of a Certificate of Approval may subsequently be tested for approval biennially instead of annually if it so elects, until such time as its results in a proficiency survey fail to justify a certificate of approval. 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 this Article. If a laboratory is required to be tested annually under the provision of Section 5.1, the certificate shall be in effect to the end of the calendar year following the year in which the proficiency survey was completed. If a laboratory eligible for biennial testing Section 5.1 satisfactorily completes the required proficiency survey, it shall receive a Certificate of Approval which shall be in effect to the end of the second calendar year following the year in which the proficiency survey was completed.

5.4. A Temporary Certificate of Approval may be issued by the West Virginia department of health to a laboratory for a period sufficient to enable the laboratory to complete the next proficiency survey; see Section 6.3.

5.5. 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. If there be an assistant to the director (as defined in 16-1, Series) his name should also be listed. A certificate shall be void if there is change of direction, or detrimental change in location or technique; or unethical practice as determined by the West Virginia board of health.

Section 6. Sensitivity and Specificity Standards for Approval.

6.1. During the initial period of testing laboratories for approval in West Virginia (which began in 1939), it was deemed advisable that standards be more lenient than American Standards, but that American Standards for the approval of intrastate laboratories by a State Health Officer be adopted as soon as feasible for West Virginia. (See "The Serodiagnosis of Syphilis," Supplement No. 9 to Venereal Disease Information: 1939, page 87.)

6.2. 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.

6.3. A Temporary Certificate of Approval may be issued by the West Virginia department of health in certain cases where circumstances clearly justify such action, such as:

1. to a currently approved laboratory under a new director whose qualifications meet the requirements of 16-1 Series.
2. to a laboratory which successfully completes $\frac{1}{2}$ of a proficiency survey to the degree of accuracy specified in Section 6.2 of this regulation;
3. to a laboratory which has successfully completed the last 3 annual

or biennial proficiency surveys preceding its failure in a current proficiency survey, provided its director or serologic worker receives refresher training in serologic techniques if indicated, and provided it sets up a satisfactory means for inter-laboratory check on its results (as by sending at least 6 "check" specimens per month, and its results thereon, to the Hygienic Laboratory for parallel testing).

Section 7. Consultants - There may be paid consultants to the hygienic laboratory director, not to exceed 5 persons. They must be recommended by the hygienic laboratory director and approved by the state director of health. The purpose of these consultants is to confer with the hygienic laboratory director to assist in interpretation of regulations, development of evaluation techniques, and the like.

Section 8. Reporting of Reactive Serologic Tests Required for Laboratory Certification. - Approval of laboratories in West Virginia for syphilis serology shall be contingent on complete compliance with Chapter 2, Communicable Diseases, Article 4, requiring laboratories to report results of all reactive (positive) serologic tests for syphilis to the state director of health. The reporting of reactive serologic tests for syphilis as a requirement for laboratory certification shall not be construed to mean that any other uncertified or unapproved laboratory is exempt from the reporting obligations of Reportable Disease Regulations

WEST VIRGINIA DEPARTMENT OF HEALTH
AGREEMENT OF LABORATORY FOR APPROVAL OF
SEROLOGIC TESTS FOR SYPHILIS

(NOTE: Wherever the term director of health is used it should be interpreted to mean the director of the West Virginia department of health, or his authorized representatives.)

TheLocated at.....

(Exact name of laboratory)

Address (Street and City)

West Virginia, in connection with its request for approval of its serological tests for syphilis, hereby agrees:

1. That the conduct of said laboratory will be in accordance with recognized standards of ethics.
2. To examine and render reports on specimens submitted from time to time by the director of health for purposes of testing the efficiency and accuracy of procedures used in said laboratory.
3. That the director of this laboratory, or the assistant to the director (both of whose education and experience comply with minimum requirements) shall devote his full time to the work of this laboratory and will have full authority and responsibility for all laboratory results and reports issuing from said laboratory.
4. To notify the director of health at once in writing of any change in this laboratory regarding:
 - (a) location or (b) active directing personnel.
5. Not to state, publish or imply that said laboratory is approved by the West Virginia department of health for any tests other than those specifically named on the certificate which may be issued to said laboratory.

Board of Health
Legislative Rule 16-1
Series VIII

State of W. Va., County of.....

Dated at..... this day of19.....

(1) Signature of Superintendent of Hospital
or Institution

(2) Signature of Director of Laboratory

(3) Signature of Assistant to the Director

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-1
Series VI
(1983)

Requirement for Laboratories to Report Reactive
Serologic and Other Tests for Syphilis to the
State Department of Health

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-1
Series VI
(1983)

Requirement for Laboratories to Report Reactive
Serologic and Other Tests for Syphilis to the
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Requirement for Laboratories to Report Reactive
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WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-1
Series VI
(1983)

Subject: Requirement for Laboratories to Report Reactive Serologic and Other Tests for Syphilis to the State Department of Health.

Section 1. General

1.1. Scope - These legislative rules establish the requirement to report reactive serologic and other tests for syphilis.

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

1.3. Filing Date - These rules were filed on the 30th day November 1964, in the Secretary of State's office.

1.4. Effective Date - These legislative rules became effective on the first day of December 1964.

1.5. Refiling Date - These legislative rules were refiled pursuant to Chapter 29A, Article 2, Section 5 of the West Virginia Code of 1931, as amended on the 30th day of December 1982, in the Secretary of State's office.

Section 2. Application and Enforcement

2.1. Application - These legislative rules apply to all laboratories that perform serologic or other tests for syphilis.

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

Section 3. Reporting Requirements

3.1. Supervisors of all laboratories in West Virginia that perform serologic or other tests for syphilis shall make a report of all positive or reactive laboratory tests for syphilis to the West Virginia state director of health on forms provided for the purpose as follows:

3.1.1. All reactive (positive) and weakly reactive (doubtful) serologic tests for syphilis.

3.1.2. All reactive (positive) and weakly reactive (doubtful) spinal fluid serologic tests for syphilis.

3.1.3. All positive darkfield microscopic tests for *treponema pallidum*.

3.2. These reports shall include:

3.2.1. The name of the laboratory.

3.2.2. The name of the test, the date performed, and the result.

3.2.3. The name and location of the physician who submitted the specimen.

3.2.4. The name of the patient, and (if available) the sex, age, and address.

3.2.5. The signature of the supervisor of the laboratory.

3.3. Reports of the above named laboratory tests shall be submitted on the 1st and 15th of each month, except positive darkfield tests which shall be submitted within 24 hours. If no reportable tests are performed during any reporting period, a statement to this effect shall be submitted by the supervisor of the laboratory.

3.3.1. The state director of health or his authorized representatives shall work through the patient's physician in any follow-up of the aforementioned reports of positive laboratory tests.