

John D. Rockefeller IV
Governor



L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

NOTICE OF PUBLIC HEARING

FILED IN THE OFFICE OF
JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 11-17-81
Administrative Law Division

Pursuant to Section eight, Article three, Chapter twenty-nine-A of the Code of West Virginia, one thousand nine hundred thirty-one, as amended, the Regulatory Services Program of the West Virginia Department of Health shall convene a public hearing at 10:00 A.M. on Monday, December 21, 1981 in the Conference Room of the West Virginia Department of Health, Room 522, 1800 Washington Street, East, Charleston, West Virginia for the purpose of taking evidence pertaining to the filing of the Approval of Laboratories for Syphilis Serology.

Any citizen or other interested party may appear in person to present evidence. Any citizen or other interested party may submit written evidence to the West Virginia Department of Health, Regulatory Services Program, Room 416, 1800 Washington Street, East, Charleston, West Virginia 25305 not later than 5:00 P.M. Monday, December 21, 1981.

The issues to be heard shall be limited to the actual information contained in the above mentioned proposed regulation. Copies of the regulation may be obtained from the Regulatory Services Program, address heretofore appearing or by telephoning 304-348-2411.


L. Clark Hansbarger, M.D.
Director

Entered November 17, 1981

Approval of Laboratories for Syphilis Serology

West Virginia Administrative Regulations
Board of Health

Chapter 16-1
Series VIII
1981

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West Virginia Administrative Regulations
Board of Health

Chapter 16-1
Series VIII
1981

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE _____
Administrative Law Division

Subject: Approval of Laboratories for Syphilis Serology

Section 1. General Method

The method of testing and approving eligible applicants shall be the method adopted in 1930 by the West Virginia Department of Health. The purpose is to appraise proficiency of performance of a specified standard serologic test for syphilis.

Section 1. General

1.01. Scope - These regulations establish the method of testing and approving laboratories for syphilis serology by the West Virginia Department of Health.

1.02. Authority - These regulations are issued under the authority of Chapter 16, Article 1, Section 7, Subsection (6) of the West Virginia Code of 1931, as amended. Reference to Chapter 48, Article 1, Section 6a of the West Virginia Code of 1931, as amended.

1.03. Filing Date - These regulations are promulgated on the _____ day of _____, _____, and are filed on the _____ day of _____, _____, in the Secretary of State's office.

1.04. Effective Date - These regulations become effective on the _____ day of _____, 1981.

Section 2. Supersession and Repeal of Former Regulations - These regulations supercede and repeal State Board of Health Regulations Chapter 4, Article 2 "Approval of Laboratories in West Virginia for Syphilis Serology.

Section 3. Application and Enforcement

3.01. Application - These regulations apply to all laboratories seeking certification under Premarital, Prenatal or Barber/Beautician Laws for syphilis serology by the West Virginia Department of Health.

3.02. Enforcement - Enforcement of these regulations is vested in the Director of the West Virginia Department of Health or his designee.

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

4.01. 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 Army, Navy, Marines, Military Service and the Public Health Service.

4.02. Except for the aforementioned ~~official~~ laboratories, a laboratory ~~eligible for approval~~ seeking approval shall:

1. be located in West Virginia;
2. show that it complies with Article 5 Chapter 16-1, Series VII Reportable Diseases Regulations;
3. complete ~~questionnaire~~ director qualification, personnel qualification, and agreement forms (HE-C and HE-D) ~~form HE-C annually and form HE-D~~ when a laboratory requests approval for the first time or when there is ~~change of direction~~ a change in laboratory director ;
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 ~~this Article (Section 4)~~ these regulations (Section 6).

Section 5. Testing Periods Proficiency Surveys and Duration of Certificates of Approval

5.01. ~~Testing of eligible laboratories applying for approval shall be carried out once annually by means by 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.

5.02. 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.

5.03. A Certificate of Approval shall be issued to a laboratory which satisfactorily completes the required proficiency survey in accordance with ~~this Article~~ these regulations. ~~If a laboratory is required to be tested annually under the provision of Section 3, paragraph a, the~~ 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 3, paragraph a.) 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.

d. 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 4, b.

5.04. 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 Article 5 of this chapter) his name should also be listed. A certificate shall be void if there is a change in direction, or detrimented change in location or technique, 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

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 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.)

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.

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 Article 5;
2. 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 5. 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 6. 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.

(a) 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 Chapter 2, Communicable Diseases, Article 4, Regulations of the West Virginia State Board of Health.

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

(Note: Wherever the term Director of Health is used it should be interpreted to mean Director of the West Virginia Department of Health or his authorized representatives.)

The Located 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 results 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. State of W. Va. County of

Dated at this day of 19.....

(1) Signature of Superintendent of Hospital or Institution

(2) Signature of Director of Laboratory

(3) Signature of Assistant to the Director

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 affected persons desiring a public hearing shall do so in a manner prescribed in and by the West Virginia Rules of Procedure, West Virginia Board of Health, Chapter 16-1,

Series I and further identified as Rules of Procedure for Contested Case Hearings and Declaratory Ruling. The aforementioned rules of procedure are incorporated by reference.

Section 9. Severability - If any provisions of these regulations 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 regulations which can be given effect without the invalid provisions or application, and to this end the provisions of these regulations are declared to be severable.

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