

John D. Rockefeller IV  
Governor



L. Clark Hansbarger, M.D.  
Director

# State of West Virginia

DEPARTMENT OF HEALTH  
CHARLESTON 25305

## Notice

Legislative Rule: Approval of Laboratories for Syphilis Serology

The above titled legislative rule was submitted to the Legislative Rule Making Review Committee on June 2, 1982.

A handwritten signature in cursive script, appearing to read "L. Clark Hansbarger", written over a horizontal line.

L. Clark Hansbarger, M. D.  
Secretary  
West Virginia Board of Health

June 2, 1982  
Entered

FILED IN THE OFFICE OF  
A. JAMES MANCHIN  
SECRETARY OF STATE  
THIS DATE 6/7/82

John D. Rockefeller IV  
Governor



L. Clark Hansbarger, M.D.  
Director

# State of West Virginia

DEPARTMENT OF HEALTH  
CHARLESTON 25305

## Certification

Legislative Rule: Approval of Laboratories for Syphilis Serology

The above titled legislative rule constitutes the official rule approved by the West Virginia Board of Health on January 22, 1982 and filed pursuant to law in the Office of the Secretary of State, State of West Virginia.

A handwritten signature in cursive script, appearing to read "L. Clark Hansbarger".

L. Clark Hansbarger, M. D.  
Secretary  
West Virginia Board of Health

June 2, 1982  
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A. JAMES MANCHIN  
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PROPOSED

WEST VIRGINIA LEGISLATIVE RULES  
BOARD OF HEALTH

APPROVAL OF LABORATORIES FOR SYPHILIS SEROLOGY

FILED IN THE OFFICE OF  
A. JAMES MANCHIN  
SECRETARY OF STATE  
THIS DATE 6/7/82

APPROVAL OF LABORATORIES FOR SYPHILIS SEROLOGY

Chapter 16-1  
Series VIII  
(1983)

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WEST VIRGINIA LEGISLATIVE RULES  
BOARD OF HEALTH

Chapter 16-1  
Series VIII  
(1983)

Subject: Approval of Laboratories for Syphilis Serology

FILED IN THE OFFICE OF  
A. JAMES MANCHIN  
SECRETARY OF STATE  
THIS DATE 6/7/82

~~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 legislative rules establish the method of testing and approving laboratories for syphilis serology by the West Virginia department of health.

1.02. 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.

1.03. Filing Date - These legislative rules were promulgated on the \_\_\_\_\_ day of \_\_\_\_\_, and were filed on the \_\_\_\_\_ day of \_\_\_\_\_, in the Secretary of State's office.

1.04. Effective Date - These legislative rules became effective on the \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

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

3.01. 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.

3.02. 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

4.01. 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; 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.

3. complete ~~questionnaire~~ director qualification, personnel qualification, 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~~ 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.~~

~~or 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 interlaboratory 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 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.

John D. Rockefeller IV  
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L. Clark Hansbarger, M.D.  
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# State of West Virginia

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WEST VIRGINIA LEGISLATIVE RULES  
BOARD OF HEALTH

APPROVAL OF LABORATORIES FOR SYPHILIS SEROLOGY

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APPROVAL OF LABORATORIES FOR SYPHILIS SEROLOGY

Chapter 16-1  
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BOARD OF HEALTH

Chapter 16-1  
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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

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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 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.

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