

**Vermont Department of Health
Application for Approval
to Perform HIV Tests for
Vermont Insurance Coverage**

Name of Laboratory _____

Address of Laboratory _____

Telephone _____

Contact Person (if
different from director) _____

Telephone _____

Please enclose:

- _____ 1. Completed and signed checklist
- _____ 2. Credentials of Scientific Director, Supervisors and Analysts
- _____ 3. Results from last two C.A.P. (or equivalent) HIV proficiencies (unless results are furnished to the VT Department of Health by proficiency agency)
- _____ 4. Non-refundable check
 - ___ Initial Application Fee: \$500.00
 - ___ Annual Renewal Fee: \$300.00
- _____ 5. Copy of HIV serology report form(s)
- _____ 6. Copy of current CLIA certificate

Send to: **Cara Bryce-Parrott**

Mailing Address:

**VT Department of Health
Public Health Laboratory
PO Box 1125
Burlington, Vermont 05402-1125
(802) 338-4729**

Physical Address:

**VT Department of Health
Public Health Laboratory
359 South Park Drive
Colchester, Vermont 05446**

**VERMONT DEPARTMENT OF HEALTH
HIV TESTS FOR VT INSURANCE COVERAGE
LABORATORY APPROVAL CHECKLIST**

1) Personnel

Scientific Director is a doctorate-level individual who has qualified as a clinical laboratory director under the Health Care Finance Administration or Clinical Laboratory Improvement Act regulations.

Yes _____ No _____

Supervisor is:

- a) a physician, or has a doctoral degree in one of the chemical, physical or biological sciences, and has had at least two years of experience in one of the laboratory specialties in an approved laboratory, or
- b) holds a master's degree with a major in one of the chemical, physical or biological sciences, and has had at least four years of pertinent laboratory experience of which at least two years have been spent working in the designated laboratory specialty, or
- c) is qualified as a clinical laboratory technologist pursuant to provisions of the Code of Federal Regulations, HFCA, Subpart M, Section 405.1315 (b) (1), (2), (3), (4), or (6), and has had at least six years of pertinent laboratory experience of which at least two years have been spent working in the designated laboratory specialty in an approved clinical laboratory.

Yes (please indicate) _____ No _____

- a) _____
- b) _____
- c) _____

Analysts have at least a bachelor's degree in Medical technology, biochemistry, medical technology, biology, or microbiology and have at least one year of pertinent laboratory experience and have been thoroughly trained in HIV testing methodology.

Yes _____ No _____

2) Quality Assurance

Do you have a quality assurance program?

Yes _____ No _____

Are a negative, and both high and low positive controls run with each sample batch?

Yes _____ No _____

7) Confidentiality

Do you agree to keep all reports confidential under the approval guidelines?

Yes _____ No _____

8) Informed Consent

Will you assure that informed consent is obtained from all persons being tested, as set forth in Section 4.2 of the regulations?

Yes _____ No _____

9) Approval

Do you understand the Application fee is non-refundable and you must pay for any travel expenses involved in a site visit, if a site visit is required?

Yes _____ No _____

If you answered "NO" to any of the checklist questions you may not be eligible for approval. Do not send in the approval fee. If you answered "NO" and wish to qualify your answer please send in an explanation with the application. Your explanation will be addressed in writing.

I hereby certify that this application checklist and the enclosed proficiency and personnel records contain no false information and are complete to the best of my knowledge. I am aware that if an investigation discloses misrepresentation or falsification, my laboratory will be ineligible to perform HIV testing for insurance purposes on residents of the State of Vermont.

Date

Laboratory Director Signature

Date

Notary Public Signature

Tests for Human Immunodeficiency Virus

Please complete the test chart as applicable.

Sample	Format	Tradename	Manufacturer
Serum	EIA		
Serum	WB		
Dried Blood Spot	EIA		
Dried Blood Spot	WB		
Urine	EIA		
Urine	WB		
Oral Mucosal Transudate	EIA		
Oral Mucosal Transudate	WB		
Finger Stick Whole Blood Or Venipuncture Whole Blood	EIA		
Other			

Vt. Department of Health
December 2005

Administrative Guidelines for the Approval of Laboratories for Vermont Insurance HIV Testing

1. General Provisions

1.1 These guidelines, as authorized by 8 V.S.A., Chapter 129, Section 4724, provide for the approval of laboratories performing Human Immunodeficiency Virus (HIV) related tests in connection with application for insurance coverage in Vermont. Testing for infection with HIV must be as correct as technically possible and all testing information must be treated with the highest regard for confidentiality. The following guidelines establish the criteria which laboratories must meet in order to be approved to perform and report testing for HIV infection in connection with application for insurance coverage in Vermont.

1.2 General Provisions

1.2.1 Enforcement

The Commissioner of Health (hereinafter called the Commissioner) may enforce these guidelines as necessary to protect the public health by exercising the authority granted the Commissioner by 18 V.S.A., Chapters 1, 3 and 21.

1.2.2 Severability

If any provision of any section of these guidelines or the application thereof to any firm, individual or circumstance is found by a court of competent jurisdiction to be illegal, invalid or void, the remainder of these guidelines shall be deemed unaffected and shall continue in full force and effect.

1.3 Procedure for Application

1.3.1 Application for Approval

- a) Each single HIV testing laboratory (not a parent corporation) which wishes to obtain approval as a Vermont insurance HIV testing laboratory shall make such a request in writing to the Vermont Department of Health (hereinafter called the Department).
- b) The Department shall, within thirty (30) days of receiving the request, provide the applicant with an application form, an approval checklist and a copy of these guidelines.
- c) The applicant must complete the application and checklist forms, sign the statement of compliance, and return these materials to the Department with copies of the laboratory's last two proficiency reports, appropriate personnel credentials and a non-refundable fee of \$500.00. These materials must be returned to the Department no later than sixty (60) days from the initial date of request by the laboratory.

1.3.2 **Action upon Application**

- a) Within ninety (90) days after receiving the materials requested in 1.3.1(c), the Department will review the information provided. The Department may request additional information for clarification purposes as necessary. (The applicant must respond to a request for additional information within thirty (30) days after the date the request was made.
- b) Upon a successful demonstration that the application is complete, the Department may conduct an on-site observation and evaluation of the laboratory to determine if the laboratory meets the requirements contained in these guidelines. The cost to the Department of an on-site observation and evaluation, including travel, food and lodging shall be at the expense of the applicant. Visitation may be waived if the laboratory meets the requirements of the alternate approval (1.3.3).

1.3.3 **Alternate Approval**

- a) The Department will accept laboratory certification pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations in lieu of the Department's guidelines. Irrespective of a laboratory's CLIA certification/approval, the requirements specified in these guidelines (2.2.4) dealing with test results and confidentiality must be met.
- b) Laboratories desiring to test Vermont samples under this subsection must notify the Department in writing of such intent, and submit evidence of their alternate certification, copies of the two most recent sets of proficiency data and a fee of \$300.00.

1.3.4 **Denial of Application**

The Commissioner may deny an application for approval to any applicant who fails to meet the standards established by these guidelines, including, but not limited to:

- a) Failure to demonstrate the ability of the applicant to comply fully with applicable requirements, procedures, and standards set forth in these guidelines.
- b) Past history of incompetence or negligence on the part of the applicant and/or his employees or agents.
- c) Submission of false information on an application.
- d) Failure to submit the required information and/or documentation with the application.
- e) Any past violations of state or federal law pertaining to HIV testing-related activities.

1.3.5 **Suspension or Revocation of Approval**

The Commissioner may suspend, modify, or revoke any approval given under these guidelines by the authority granted in 18 V.S.A., Chapter 3, Section 123.

1.3.6 **Expiration of Approval Status**

Approved status shall expire on the last day of the calendar year.

1.3.7 **Renewal of Approval Status**

a) Any request for a renewal of approval issued under these guidelines shall contain all the information requested by these guidelines without reference to previously submitted materials.

b) Any request for a renewal of approval must be accompanied by an annual renewal fee of \$300.00.

1.3.8 **Subcontracting**

All laboratories performing any screening and/or confirmation tests, related to Vermont insurance HIV testing, regardless of whether the laboratory has been subcontracted to do so by an approved laboratory, must be approved pursuant to these guidelines.

2. **Approval of Laboratory Services**

2.1 **Applicability**

No firm or individual shall directly or indirectly provide any HIV testing services to an insurer in Vermont without first being approved by the Commissioner under these guidelines to provide such services.

2.2 **Requirements for Approval**

2.2.1 **General Requirements**

To be approved as a Vermont insurance HIV testing laboratory, the party seeking approval shall apply to the Department in accordance with Section 1.3 of these guidelines. The laboratory shall allow the Department to perform on-site inspections of its facilities, equipment and records.

2.2.2 **HIV Analysis**

a) **Proficiency Testing**

To be approved as a Vermont insurance HIV testing laboratory, the party must participate in a Department recognized proficiency testing program (College of American Pathologists or equivalent). The laboratory shall show satisfactory performance on the last two test events in the proficiency testing program to be

eligible for approval. The laboratory shall continue to participate in all testing rounds available from the program to maintain approval and send copies of HIV proficiency test results to the Department after each round of testing.

b) **Proficiency Testing Results**

If any proficiency test results are unsatisfactory according to preestablished criteria, the laboratory must determine and correct the cause of non-proficiency. A report of the findings together with remedial actions, must be recorded, dated, and signed by the supervisor and laboratory director. This report shall be mailed to the Department within thirty (30) days of the unsatisfactory proficiency test results.

2.2.3 **Methodology**

a) **Initial Screening**

The laboratory may utilize enzyme immunoassay (EIA), or an equivalent technology if approved to do so by the Department, in performing the initial screening test. The initial test must be licensed by the U.S. Food and Drug Administration for non-donor screening (diagnostic testing).

- i) All positive screening tests must be repeated on another aliquot of the same specimen. Positive screening test results shall not be reported until a confirmation test has been performed.
- ii) Specimens which initially test negative need not be retained or confirmed.

b) **Confirmation Testing**

All samples which have tested repeatedly positive by the initial testing must be confirmed by a licensed Western Blot assay or other equally or more reliable confirmatory test protocol approved by the Commissioner and the U.S. Food and Drug Administration. Confirmation testing may be performed by a reference laboratory, provided such laboratory is approved pursuant to these guidelines and reports the testing results only to the laboratory submitting the specimens.

c) **Control Specimens**

A positive control and a negative control specimen must be analyzed with each batch of specimens tested using the EIA procedure. A high and low positive control and a negative control specimen must be analyzed with each batch of specimens tested using the Western Blot procedure. With all procedures used, the manufacturer's instructions must be rigorously followed. Internal controls, blind to the analyst, shall be tested periodically, but no less than quarterly.

2.2.4 **Test Results**

- a) All test results, including screening, confirmation and quality control data must be reviewed by the scientific director and/or supervisor before being certified as

accurate. The report shall identify each test performed, whether the results are positive, negative or indeterminate and the positive bands for Western Blot procedures.

- b) All test results shall be confidential and shall be released only with written consent of the tested individual, except where such release is compelled by a court of competent jurisdiction.

2.2.5 **Quality Assurance**

The laboratory shall have in writing its quality assurance procedures to be followed during HIV testing. The laboratory shall maintain documentation available for review by the Department at the Department's request. The written report of protocol and procedures shall include but not be limited to review of:

- a) specimen acquisition
- b) specimen handling and storage
- c) reference for testing procedures
- d) replicate specimen analysis
- e) blind specimens
- f) data handling, evaluation and storage procedures.

2.2.6 **Equipment**

The laboratory shall demonstrate that it has the proper equipment and instrumentation to perform all testing procedures for which it is approved. Maintenance, repair and temperature logs, as appropriate, on all equipment shall be maintained and shall be made available to the Department upon request.

3. **Personnel**

3.1 **General Requirements**

No laboratory shall be approved to provide Vermont insurance HIV testing services without first having the properly credentialed scientific director, supervisor and analysts. The approved laboratory must notify the Department immediately upon a change in the directorship. The name of the new director and the appropriate credentials must be submitted to the Department.

3.2 **Required Personnel**

3.2.1 **Scientific Director**

- a) The scientific director shall hold a doctorate level degree and be qualified as a clinical laboratory director under the Clinical Laboratory Improvement Amendments of 1988.

- b) The director must be able to demonstrate, at onsite inspections, his/her competence in the specialized components of HIV tests, including confidentiality, security and documentation.

3.2.2 **Supervisor**

The supervisor must meet one of the following requirements:

- a) is a physician, or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and subsequent to graduation has had at least one year of training or experience, or both, in the laboratory specialty of Diagnostic Immunology; or
- b) holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and subsequent to graduation has had at least two years of laboratory training or experience, or both, in the laboratory specialty of Diagnostic Immunology; or
- c) holds a bachelor's degree in a chemical, physical or biological science, and, subsequent to graduation has had at least four years of laboratory training or experience, or both, in testing for the specialty of Diagnostic Immunology.

The supervisor shall be responsible for ensuring that there are sufficient personnel with adequate training and experience to conduct the work of the HIV testing laboratory.

3.2.3 **Analysts**

Analysts must possess at minimum an associate's degree in a laboratory science or medical technology and must be thoroughly trained in HIV testing methodology.

3.3 **Personnel Files**

3.3.1 **Documentation**

All approved laboratories must maintain a personnel file for each employee which shall include, at a minimum: certification/licenses, educational background, job description, performance evaluation, health records, incident reports, and if appropriate, results of a test for color blindness. This documentation, or any portion thereof shall be made available to the Department upon request.

4. **Documentation and Recordkeeping**

4.1 **Retention of Records**

Each laboratory shall maintain records in accordance with 4.1.1 of all HIV-related testing which it performs and shall make these records available to the Department upon request. The laboratory shall retain these records for no less than three (3) years after compilation.

4.1.1 **Required Documentation**

Each approved laboratory shall record the following information:

- a) The personnel files on each director, supervisor, analyst and all other individuals authorized to have access to specimens.
- b) Documentation of compliance with all HIV-related testing requirements.
- c) Documentation of accreditation inspections, including performance records on proficiency tests and quality assurance/quality control records.
- d) The methodology and results of all HIV-related testing, including the name of each individual performing the test and the name of each individual verifying the test results.
- e) Documentation of all test samples returned to insurers for failure to include a verification of informed consent in accordance with 4.2.

4.2 **Informed Consent**

Each sample received by the laboratory for testing must be accompanied by verification from the insurer that the individual, on whose sample the test is being performed, received full written disclosure on the nature of the HIV test, and gave written consent to the performance of such a test.

Any sample received without the necessary verification must be returned, untested, to the insurer.