

**Clinical Laboratory Program**

99 Chauncy Street, 2<sup>nd</sup> Floor, Boston, MA 02111  
(617) 753-8439/8438 (617) 753-8240 - Fax

**GUIDELINES FOR HIV [Non-Waived] TESTING**

TO: Requesters of HIV [non-waived] Test Approval

Laboratories that wish to perform HIV testing [non-waived] must be approved by the Department prior to beginning testing. The following information needs to be submitted for review in order to make a determination concerning the facility's compliance with applicable state licensure regulations, *M.G.L. 111 § 70F* and *105 CMR 180.000 Rules and Regulations Relating to the Operation, Approval and Licensing of Laboratories* [Special Requirements - Viral Serology [180.300].

- Evidence of Proficiency Testing Enrollment.
- Written request for the addition of the specialty, Immunology and the sub-specialty, Viral Serology (HIV Testing)
- Sample of laboratory request and final report.
- Documentation of arrangement for re-examination of positive patient specimens.
- Documentation of arrangement for a confirmatory test for a positive specimen.
- Written policies to assure confidentiality of test results and other patient information.
- Written policies which ensure patient consent for the test prior to the test being performed including:
  - Voluntary nature of tests for non-blood donors.
  - Purpose of the test.
  - Interpretation of the test including significance and limitations.
  - Availability of confirmatory tests.
  - Availability of additional information and counseling.
- Documentation that the test has been approved by an internal review mechanism within the hospital or clinic, if applicable.

Please be advised that no patient testing or reporting may be performed until the facility has received approval from this Division.

Send or fax the above documentation to:

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**Guideline for HIV [non-waived] Test - continued**

180.030(A)

Evidence of enrollment in an approved proficiency testing program for HIV antibody can be satisfied in one of the following ways:

1. Submit to the Department a copy of a completed subscription application.
2. Submit to the Department a copy of the order form and canceled check.
3. Submit to the Department a copy of a proficiency testing report which has been evaluated by the proficiency testing service.

180.030(D)

A request to perform HIV testing at a facility or to accept specimens for HIV testing to send to another laboratory must be in writing in the form of a letter. The letter should specify whether the test will be performed on blood donors and/or non-blood donors.

180.290(B)

The Laboratory Director is responsible for maintaining the confidentiality of test results. A copy of the test procedure which indicates how test results are to be reported and recorded must be submitted to the Department.

180.300(A)

The laboratory must submit a copy of the test procedure to the Department. The procedure must include criteria for repeat and confirmatory testing and the name of the laboratory where the test will be performed.

180.300(B)

A written statement addressing the laboratory's policy regarding patient confidentiality shall be submitted to the Department.

180.300(C)

A patient consent form must be submitted to the Department. This form must explain:

1. That the test is voluntary for non-blood donors.
2. Why the test is being performed.
3. The interpretation of the test - what a positive and/or a negative result may mean to the patient.
4. Where and under what circumstances a confirmatory test will be performed.
5. Where additional information and counseling can be sought.

180.300(D)

Policies and procedures for the above must be submitted to the Department. Such policies are necessary to perform a survey by mail.

All hospital and clinic laboratories must submit evidence that the HIV testing policies have been approved by an internal review mechanism. This mechanism can be an already established committee at the hospital or clinic, such as the Infectious Disease Committee, or a newly established ad hoc committee.

Evidence of review can be satisfied by:

1. A letter from the chairman of the committee.
2. A copy of the minutes of a meeting held by the committee.