

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Care Quality
Clinical Laboratory Program
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August 28, 2012

TO: Clinical Laboratory Directors

FROM: Roberta Teixeira, Clinical Laboratory Program

DATE: August 28, 2012

RE: Clarification of laboratory requirements related to HIV testing (105 CMR180.300(C)), release of HIV test results (M.G.L. c. 111D, s. 8), and recent changes to M.G.L. c. 111, s. 70F

The purpose of this letter is to explain a recent change to M.G.L. c. 111, s. 70F, which has been the basis of several recent inquires related to clinical laboratories, consent for HIV testing, and release of test results back to the ordering clinician.

The recent change to M.G.L. c. 111, s. 70F¹ represents only a change to the consent process for HIV testing. The law now allows for verbal informed consent from the individual being tested; written consent for HIV testing is no longer required. The confidentiality protections for the **release** of results of an individual's antibody or antigen test or for the **release of medical records** containing such information remain: the law requires written informed consent. The change in the law took effect on July 26, 2012. This change in the law does not affect the reporting of completed HIV test results to the ordering clinician.

Question: Does the law require written patient consent in order to test the patient for HIV?

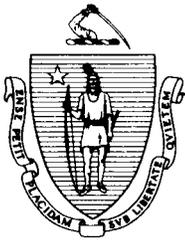
Answer: The law only requires verbal consent for testing, which covers every phase of the test process. .

Relevance to Clinical Laboratories: As currently written, 105 CMR 180.300 (C) requires laboratories to have written procedures ensuring that the clinician ordering an HIV test has obtained written consent from the patient. As a result of the change in the law, the clinician may now obtain verbal consent from the patient, so the laboratory no longer needs to comply with 105 CMR 180.300(C), which is now out of date. It is the responsibility of the clinician (not the laboratory) ordering the test to secure consent, which may now be verbal consent. If your facility policy currently requires that written consent must accompany laboratory orders for HIV screening, this is now not legally necessary.

Question: Does the release of an HIV test result back to the ordering clinician require written consent?

Answer: No. Reporting lab results back to the ordering clinician is standard practice.

¹ [Session Laws: CHAPTER 84 of the Acts of 2012](#)



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Relevance to Clinical Laboratories: M.G.L. c. 111D, s. 8, allows clinical laboratories licensed in the Commonwealth to report completed test results back to the ordering clinician without any further consent from the patient.

Question: Does the ***CLINICAL ADVISORY: ROUTINE HIV SCREENING IN MASSACHUSETTS*** ([Routine HIV Screening and Changes to Massachusetts Law Governing Consent - July 2012 - Health and Human Services - Mass.Gov](#)) released by the Department of Public Health in response to this legal change to M.G.L. c. 111, s. 70F change the practice of laboratories receiving an order for an HIV test, processing the test and returning the results to the ordering physician?

Answer: No. The intention of the ***Clinical Advisory*** is to describe the legal changes to the consent requirement for HIV testing to clinical providers/clinical facilities, and to illustrate the legal constraints regarding sharing HIV status or medical records containing such information through electronic medical records with other providers or other facilities.

Relevance to Clinical Laboratories: The ***Clinical Advisory*** should not alter current clinical laboratory practice for HIV testing.

Please note:

At the present time, the clinical laboratory regulations, 105 CMR 180.000, are undergoing a comprehensive revision. The new draft will remove any outdated regulations with respect to HIV testing. When the draft is finalized, a public hearing will be held according to legal requirements.

Thank you.