

New York State Department of Health

Clinical Laboratory Evaluation Program

Guidance for Direct Access Testing

Are laboratories required to accept orders directly from consumers?

No. As a business, a laboratory is free to choose its customers. Public Health Law simply allows laboratories to accept orders for certain tests without medical authorization. Laboratories may choose to offer only some of the eligible tests through direct access, and retain the more conventional practitioner-ordering model for other tests. For example, the statutory obligations for protection of confidentiality, informed consent and counseling, etc. associated with HIV tests may be beyond the capability of some laboratories, or, at the least, make less attractive the direct access marketing of HIV tests. In such a case, a laboratory would be free to make a business decision not to offer that test on a direct access basis. Laboratories need to also consider the potential for substantial change to their service delivery and billing processes when deciding whether to enter the direct access market.

What tests can laboratories offer directly to consumers?

A list of the tests approved for OTC sale by the FDA's Center for Devices and Radiologic Health (CDRH) is posted at www.fda.gov/cdrh/oivd/consumer-otcdatabase.html. A separate FDA branch, the Center for Biologics Evaluation and Research or CBER, has approved an at-home collection device for HIV antibody testing. Therefore, although it does not appear on the CDRH list, a test to detect antibodies to HIV may be offered directly to consumers, provided the laboratory can meet existing requirements related to such testing, including informed consent, pre- and post-test counseling, confidentiality and reporting of confirmed positive results to the Department as set forth in Part 63 of Department regulations. NOTE: The FDA's OTC approval of tests and devices is specimen-specific and typically designates the specimen type(s) that may be used, e.g., whole blood, serum, urine, or hair. PHL allows direct access whenever "the clinical laboratory service is for the **same purpose** as a test or collection device that has been approved or cleared by the FDA." The Department interprets this language as allowing laboratories to accept a consumer's order for a test that uses a different specimen type/matrix than that specified in the OTC test's package materials. For example, a laboratory could conceivably offer an immunoassay for serum β -hCG as a "pregnancy test" since a urine dipstick test is available OTC for the same purpose, i.e., detection of pregnancy. Use of devices FDA-approved for over-the-counter commercialization is not required, however, all tests used by the laboratory for direct access testing must be FDA-approved and used unmodified. Laboratories that wish to use in-house developed tests or other tests that are not FDA-approved should contact the Department for a determination as to whether use in direct access testing is appropriate.

Who may directly access laboratory testing?

The law provides for direct-access testing upon "the request of the person on whom the service is to be performed." Therefore, the laboratory must verify that the person who provides the specimen for testing is the same person who is informed of the test results. When a test subject presents him or herself at the laboratory, at an approved permanent collection site (a patient service center) or at a temporary health fair location for specimen collection or to provide a self-collected specimen, the laboratory must document that some type of picture identification, such as a driver's license, has been presented. Photo-ID information noted at the time of specimen collection would need to be verified whenever results, written or oral, are given in person, except whenever the test subject remains on-site to await results of rapid testing conducted at the point of collection. There may be situations in which a laboratory distributes a collection kit and consumers may self-collect a specimen in the privacy of their homes, for subsequent mailing to the laboratory for testing. In such cases, whenever the laboratory expects to report test results over the telephone or by electronic means, it must assign a unique identifier to each device user, and must verify that identifier prior to the reporting of results.

HIV testing may not be made available by mail order, over the Internet, or in any setting where the test subject does not present for counseling. It is the Department's position that HIV testing should be available only when counseling necessary for informed consent can be face-to-face, and when identity of the source of the specimen can be verified. To do otherwise would frustrate Department efforts toward maintaining confidentiality, facilitating medical intervention and offering guidance to infected individuals and their contacts.

Laboratories offering direct-access testing must establish criteria for determining whether an individual who presents for direct-access testing has the legal authority and capacity to consent for testing. The following may be helpful:

- Minors (persons under the age of 18) cannot legally consent for health care and therefore may not order laboratory tests on themselves under the direct-access law, except as follows: (1) pregnant minors can legally consent for medical services relating to prenatal care; (2) minors who are parents and married minors can give consent for their own medical care; and (3) minors may be tested for HIV if they demonstrate capacity for informed consent and can make informed decisions if the HIV test result is positive;
- Legal guardians and natural guardians (e.g., parents) may not consent for direct-access laboratory testing of their charges or children;
- All persons, especially minors, must be assessed for capacity to consent in accordance with a policy approved by the laboratory director. A laboratory may refuse to conduct a test on an individual who has been determined by the laboratory to lack capacity to consent, whether permanent (e.g., severe mental illness or disability) or temporary (e.g., drug or alcohol intoxication); and
- Since informed consent is required prior to performing direct access testing, the laboratory should consider factors such as language barriers and hearing impairment in relaying information necessary for informed consent.

Where can tests be performed?

All tests must be performed in a laboratory holding a New York State clinical laboratory permit in the appropriate category(ies). Registered limited service laboratories are not licensed clinical laboratories, and must document authorization of the physician or other health care professional who has ordered point-of-care testing as ancillary to a medical encounter, or, for public health testing, authorized by the Commissioner or a designee.

How should specimens be collected and who may collect them?

Specimens may be collected by laboratory employees, self-collected at laboratory facilities, or, with the exception of HIV tests, may be self-collected in the privacy of a consumer's home or other private setting. Whenever a laboratory distributes a collection kit and a consumer self-collects a specimen for subsequent mailing to the laboratory for testing a unique identifier must be assigned to each device if the laboratory offers test result reporting over the telephone, electronically or in any other manner except through a direct encounter with the individual tested. Persons collecting specimens or overseeing self-collection must be appropriately trained in specimen collection and labeling, and test subject identification procedures. In addition, persons who conduct counseling required for informed consent prior to specimen collection must have received training in the informed consent process, counseling, and confidentiality requirements (*See Resources Section*).

Are there any special space arrangements for direct access testing?

Specimens must be collected in an area separate from the testing facilities of the laboratory. The collection area must allow access to a bathroom if urine specimens are collected and must be otherwise equipped as a patient service center, including a working refrigerator, facilities for hand-washing, and medical waste containers. A separate and private space, such as a room with a door, must be used for HIV counseling sessions, informed consent procedures and delivery of test results.

May direct access testing be offered at health fairs?

Yes, direct access testing may be offered as part of a community-screening event at a location off-site of the laboratory facility or its PSC. The laboratory must request and be granted Department approval to operate a health fair. If such approval is already on file, but the laboratory wishes to offer services at any site under a direct access protocol, it must notify the Department.

Are there record keeping requirements specific to direct access testing?

Yes. The laboratory's accession system must clearly and affirmatively identify direct access tests as being self-ordered. The mere absence of a practitioner identifier in the accession record is not sufficient. Additionally, laboratories that offer HIV antibody screens as a direct access test will need to maintain a copy of the signed informed consent form on file. The content of the Department-approved consent form for HIV testing is explicitly provided in Part 63. Forms are available from www.health.state.ny.us/nysdoh/hiv aids/hivpartner/forms.htm. Additionally, laboratories that offer HIV antibody tests as a direct access test will need to maintain a copy of the signed informed consent form on file in a secure location that protects patient confidentiality.

Are there reporting requirements specific to direct access testing?

Subpart 58-1 requires a written report. "Written" is interpreted to mean hardcopy, and electronic format that can be printed and/or downloaded by the recipient. The requirement for a written report applies to direct access testing, except that a test subject may refuse a written report by indicating their refusal on the order form. Laboratories need only capture the test subject's name, address and other demographic information when such items are required to be reported along with test results to the Department. HIV antibody test results must be initially communicated in person, although copies may be transmitted following appropriate post-test counseling as detailed below if the test subject consents to having results mailed to a street or e-mail address. A separate room with a door or similar private space must be available to maintain confidentiality whenever any test results are reported orally. Reporting of HIV test results, including the handing of a hardcopy report to the test subject, must be accomplished in a private setting where counseling can also take place. Test results may be communicated as follows:

- Orally, in-person, provided the test subject identifies him/herself by a photo-ID (if he or she remained at the laboratory's site of collection during testing to await test results, a photo-ID is not required);
- Except for HIV tests, orally, over the telephone, provided the unique identifier assigned to the self-collection device accompanies the request for results;
- Via the mail (i.e., US Postal Service or other carrier), provided, for HIV tests, results have been communicated orally and counseling appropriate to the test result has already taken place and the test subject has consented to results being mailed;
- Electronic/telephonic transmission (i.e., over the Internet or fax machine), provided that, for HIV testing, results have been communicated orally and in-person and post-test counseling appropriate to the test result has already taken place; the fax machine or e-mailbox is secured in a way that protects confidentiality; and the test subject has consented to results being transmitted by such means;

May reports be sent directly to medical providers?

It is strongly recommended that laboratories encourage the person tested to discuss the results of any direct access testing, especially abnormal results, with his or her medical provider. Department rules contain no express prohibition against sending results directly to medical providers; however, the Department expects the laboratory to comply with federal privacy rules for transfer of personal health information, including getting the test subject to consent in writing. Be advised that many health care professionals do not wish to receive the results of tests they did not order.

Are there any limitations as to what can be included in the report?

Direct access test reports must be limited to test results and normal or reference ranges for the test or tests reported, except that a statement clearly indicating that the report should not be viewed as medical advice and is not meant to replace direct communication with a physician or other health care practitioner should be placed in a prominent position on the report. (In instances of oral reporting, such a statement is best delivered prior to communication of the test result.) Reports for drugs-of-abuse testing shall clearly indicate cutoff concentration (in lieu of normal range), whether the result has been confirmed, and the method of confirmation.

May reports contain information about the disease or condition for which testing has been requested?

Reports must clearly indicate that they should not be viewed as medical advice and are not meant to replace communication with a physician or other licensed health care practitioner. The report should, however, flag results that are outside the expected range and may indicate a need for the test subject to seek medical care.

Informational and general educational materials about the test or disease or condition being tested, and/or a list of all direct-access tests offered by the laboratory may accompany a hardcopy report. An analysis or interpretation that is specific to test subject's result is prohibited on the report or in accompanying materials. Recommendations for repeat or additional testing are prohibited. The laboratory must establish and implement a policy for handling "alert values" (i.e., substantially abnormal results that indicate a need for urgent medical attention), which includes a means of contacting test subjects who request tests with potential for "alert values."

Will the costs of direct access testing be covered by insurance?

The Direct Access Testing Law does not address how laboratories should be compensated for providing direct access testing services. Laboratory testing is a covered service under New York State Medicaid only when a qualified medical practitioner has ordered the tests. Medicare, as a third-party payor, does not pay for screening tests with a few exceptions. Since payors typically reimburse only for laboratory testing that has demonstrated medical necessity, it is unlikely that self-ordered tests would be covered by health insurance. The Department anticipates that laboratories that engage in direct-access testing will develop, and make available to the consumer at the time testing is requested, a schedule of charges and payment options.

The Department anticipates that accurate and reliable laboratory testing will be more expensive on a per-test basis than an OTC test for the same purpose. Consumers who will be faced with a choice between two methods of testing for the same analyte should be provided with true and accurate information as to why one method is more costly than another, and the amount of payment expected by the laboratory before the specimen is collected or accepted. If laboratory terms such as sensitivity and specificity are used, they should be defined in terms easily understood by the average consumer. Laboratories must provide full disclosure of costs of testing, including confirmatory testing, if any, to its direct access clients.

What are the additional requirements for HIV testing?

The new law requires that “all services conducted pursuant to this section shall comply with the standards for testing established by the department and with any other laws of this state, including requirements for confidentiality and pre-test and post-test counseling.” In addition to the requirements specific to HIV testing addressed in the guidance above, laboratories that choose to offer HIV testing directly to consumers must develop protocols to ensure that the requirements of PHL Article 27-F; PHL Article 21, Title III; and Subparts 58-1, 58-8 and Part 63 of the New York Code of Rules And Regulations (NYCRR) are met. The full text of these regulations is available on our website (*See Resources Section*). Note that laboratories performing direct access testing must comply with the obligations imposed on providers, as well as those imposed on laboratories, set out in 10 NYCRR Part 63. As such they must maintain a copy of the informed consent document signed by the test subject. Specific requirements related to HIV testing are set out in the laws and regulations noted above. The general nature of those requirements include:

- Confidentiality. Protocols for test ordering, specimen collection, payment and analysis and reporting, record keeping, counseling, and all other handling of HIV/AIDS related information must ensure that patient confidentiality is protected. Anonymous or “medically confidential” (encoded) testing is not allowed. Individuals who would prefer anonymous testing should be referred NYS Department of Health (NYSDOH) Anonymous Counseling and Testing Sites. It is highly recommended that the laboratory maintain a list of local Anonymous Counseling and Testing sites. Information about anonymous counseling and testing is available on the NYSDOH website or by telephone (*See Resources Section*).
- Counseling and informed consent. Personnel at the collection site must be trained to conduct required pre-and post-test counseling in order to obtain informed consent. A schedule of DOH-sponsored courses as well as a downloadable consent for information is available on our website (*See Resources Section*). Laboratories should provide patients who test positive (confirmed positive) for HIV with a list of local HIV treatment and service providers and information regarding partner notification assistance, in addition to providing post-test counseling. Individuals who receive negative results may be referred to local HIV/AIDS services organizations, many of which offer HIV prevention programs and intervention (*See Resources Section*).
- Testing requirements. Testing must be performed as outlined in Section 58-8.3. Please note that an amendment that would allow a single HIV test as the initial antibody screening step of the overall HIV testing and reporting algorithm becomes effective on August 13, 2003.
- Release of preliminary results. Subpart 58-8 requires the written request of a physician or other authorized person before a preliminary HIV test may be released to the individual tested. The medical professional’s decision to release a report directly to a patient would be based on his or her professional assessment of the capacity of the test subject to understand the preliminary nature of the result and to react accordingly. Therefore, a preliminary positive HIV test result (i.e., an unconfirmed positive based on 2 out of 3, or 3 out of 3 reactive screen tests) may NOT be released to the test subject of a direct access test. Negative results of HIV antibody screen tests may be released upon completion of the test and appropriate test counseling. Positive results may be released only after confirmation and as part of appropriate post-test counseling. The laboratory should prepare a consumer-oriented document to explain false positive and false negative results.
- Reporting requirements. Confirmed positive HIV results must be reported to the Department as outlined in Subpart 63-4. Such reports must clearly indicate that the HIV test was performed as a direct-access test, using “DAT” in place of the ordering practitioner’s name. Whenever a specimen is referred elsewhere for confirmatory testing, the forwarding laboratory must advise the testing laboratory that the screening test was a direct access test.

Resources

Useful Websites

- Regulations and statutes cited in this document can be obtained on our regulatory affairs website at www.wadsworth.org/labcert/regaffairs/index.htm. Information on applying for laboratory permits and application forms can be obtained on the Clinical Laboratory Evaluation Program Website at www.wadsworth.org/labcert/clep/clep.html.
- The list of test kits and collection devices approved by the FDA for over the counter (OTC) use can be obtained at <http://www.fda.gov/cdrh/oivd/consumer-otcdatabase.html>.
- Resources for HIV/AIDS, including a calendar of training courses for counseling, informed consent, and confidentiality and reporting requirements; and information on how to obtain a list of Anonymous Counseling and Test Sites, can be obtained at www.health.state.ny.us/nysdoh/aids/index.htm.

Who to contact for more information

- Questions about direct access testing services can be directed to the staff of the Clinical Laboratory Evaluation Program at (518) 485-5378, or by email to CLEP@health.state.ny.us.
- Non-technical questions about HIV testing, and information about counseling, may be directed to the AIDS Institute Bureau of Direct Program Operations at (518) 474-3671. Questions about HIV/AIDS training programs may be directed to the Institute at (518) 474-3045. Questions may also be submitted by e-mail at hivct@health.state.ny.us.