

# Survey of Direct-to-Consumer Testing Statutes and Regulations

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Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
<b>Alabama</b>	No	Ala. Admin. Code r. 420-5-8-.01(2)(1),(o) Ala. Admin. Code r. 420-5-8-.04(5)(d)(3)	While state law does not address DTC testing directly, an official in the Alabama Department of Public Health stated that DTC testing is prohibited under state law, since the Administrative Code limits ordering tests to a licensed physician or other “authorized person.”
<b>Alaska</b>	Yes	None identified	State law is silent on the issue. An official in the Alaska Department of Public Health stated that no law prohibits any person from ordering a laboratory test.
<b>Arizona</b>	Limited	Ariz. Rev. Stat. § 36-470 Ariz. Admin. Code R9-14-102	State law lists specific tests that may be ordered directly by consumers. Other than those specified tests, only health professionals authorized by law are permitted to order tests, and laboratories must report results only to the person who ordered the test. An official at the Arizona Department of Health Services confirmed that DTC testing is limited to a few specified tests.
<b>Arkansas</b>	Yes	None identified	An official in the Arkansas Division of Health Facility Services confirmed there are no laws in Arkansas that address this issue.
<b>California</b>	Limited	Cal. Bus. & Prof. Code § 1241 Cal. Bus. & Prof. Code § 1246.5 Cal. Health & Safety Code § 120917 Cal. Health & Safety Code § 123148 17 Cal. Code. Reg. 1053.5	DTC testing is expressly authorized only for specified tests: “pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit,” as well as HIV tests. A test approved only as an over-the-counter collection device may not be conducted pursuant to this section. <sup>1</sup> An official at the California Department of Health and Human Services confirmed that DTC testing is limited.
<b>Colorado</b>	Limited	Colo. Rev. Stat. § 12-36-106(3)(u) Colo. Rev. Stat. § 12-36-106(1)	An official at the Colorado Department of Public Health & Environment noted that under Colorado law, the definition of the practice of

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			medicine does not include the provision of laboratory tests to individual patients. Therefore, he stated, DTC testing is understood to be permitted. The official pointed to a section of the Colorado Revised Statutes that excludes from the practice of medicine the provision of laboratory results to a licensed physician, other than histopathology and cytology test results. While this provision of the law is somewhat ambiguous, the state official interprets it to mean that Colorado does not allow laboratories to provide histopathology and cytology tests directly to consumers.
<b>Connecticut</b>	No	Regs., Conn. State Agencies §19a-36-D29(a) Regs., Conn. State Agencies §19a-36-D32(a)	Laboratories may accept specimens only upon request of licensed physician or other persons authorized by law to make diagnoses. Laboratories may report findings only to the licensed provider that ordered the test. Laboratories may provide results to lay persons upon written request of the provider who ordered the test. An official at the Connecticut CLIA Laboratory Program confirmed that DTC testing is not permitted.
<b>Delaware</b>	Yes	None identified	State law is silent on the issue. An official with the Delaware Department of Public Health Laboratories stated that Delaware permits DTC testing without limitations.
<b>District of Columbia</b>	Yes	D.C. Code § 44-211	D.C. law does not directly address DTC testing. The law does permit patients to request, in writing, access to or copies of the results of their laboratory tests. The law also states that all clinical laboratory results shall be reported to the requesting physician, but that when there is no requesting physician the laboratory shall report the test results directly to the patient and recommend that the patient forward the results to his or her physician. An official with the D.C. Department of Health

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			stated that there is a D.C. clinical laboratory licensing law but it will not be implemented until regulations are promulgated; currently only the federal CLIA law is being enforced.
<b>Florida</b>	Limited	Fla. Stat. Ann. § 483.181(1),(2) Fla. Stat. Ann. § 483.288 Fla. Stat. § 483.314	A clinical laboratory may examine human specimens at the request only of a licensed practitioner or other person authorized by law to use the findings of clinical laboratory examinations. The results of a test must be reported directly to the licensed practitioner or other authorized person who requested it. An individual forwarding a sample of the individual's own blood to a clinical laboratory collected using an FDA approved home access HIV test kit shall be considered a person authorized to request this test. An official with the Florida Agency for Health Care Administration, Laboratory Licensing Unit, explained that only "medical" laboratory tests fall under these laws. Paternity tests, for example, do not. The official noted that it is unclear whether genetic tests that screen for a predisposition for Alzheimer's Disease or cancer, for example, would qualify as "medical" tests under these laws, as a clinician receiving these results would not necessarily make any medical decisions based on them. <sup>1</sup>
<b>Georgia</b>	No	Ga. Code Ann. § 31-22-4(a),(c)	Tests may be ordered only by a "licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations." Test results may be reported only "to or as directed by the licensed physician, dentist, or other authorized person requesting such test." An official at the Georgia Department of Human Resources confirmed that DTC testing is not permitted.
<b>Hawaii</b>	No	Weil's Code of Hawaii Rules § 11-110-12(b),(c) Weil's Code of Hawaii Rules § 11-110-	Tests may be ordered only by a "person authorized by law to receive and interpret laboratory results." Test results may be

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
		33(6)	reported only to a person authorized by law to receive and interpret laboratory results or to a referring laboratory. According to an official at the Hawaii Department of Health, new regulations, which as of 6/13/07 had not been signed by the governor but which will probably go into effect in July 2007, will specify who "authorized persons" are. The new regulations will allow designees of authorized persons (e.g. individual patients authorized by their physicians) to order tests directly from laboratories.
<b>Idaho</b>	No	IDAPA 16.03.14.350.07	A provision in the state administrative code pertaining to hospital laboratories states that "orders for tests shall be made only by those practitioners legally authorized to diagnose, treat and prescribe." An official with the Idaho Bureau of Laboratories confirmed that DTC testing is not permitted.
<b>Illinois</b>	Limited	210 Ill. Comp. Statutes 25/7-101 210 Ill. Comp. Statutes 25/9-101	State law provides that tests may be ordered only by physicians, other health professionals listed in the statute, and police officers. Test results must be provided only to the authorized person who requested it. A state official with the Illinois Department of Public Health explained that there is now a rule allowing DTC testing, but only for CLIA-waived tests. However, this rule has not been approved by an Advisory Board, as the department no longer has an Advisory Board, so it is unclear what would happen if the rule were challenged.
<b>Indiana</b>	Yes	None identified	State law is silent on the issue. An official with the Indiana State Department of Health stated that DTC testing is permitted.
<b>Iowa</b>	Yes	None identified	State law is silent on the issue. An official with the Iowa CLIA Laboratory Program confirmed that there is no state law on the issue.
<b>Kansas</b>	Yes		State law is silent on the issue. An official at

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			the Kansas Department of Health & Environment confirmed that Kansas is a direct access state.
<b>Kentucky</b>	No	Ky. Rev. Stat. § 333.150 Ky. Rev. Stat. § 333.190 Ky. Rev. Stat. § 333.240	State law provides that a “medical laboratory shall examine human specimens only at the request of a licensed physician, podiatrist, dentist, or other person authorized by law to use the findings of medical laboratory examinations. The results of a test shall be reported directly to the licensed physician, dentist, or other authorized person who requested it.” An official with the Kentucky Office of Inspector General confirmed that DTC testing is prohibited.
<b>Louisiana</b>	Yes	None identified	State law is silent regarding authorization for DTC testing. An official with the Louisiana Department of Health and Hospitals stated that there are no state laws regulating laboratories and that anyone is permitted to order a laboratory test.

## Survey of Direct-To-Consumer Testing Statutes and Regulations

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<b>Maine</b>	Limited	Me. Rev. Stat. Ann. tit. 22, § 2031-A Me. Rev. Stat. Ann. tit. 22, § 2030 Me. Rev. Stat. Ann. tit. 22, § 2031 CMR 10-144-256(9)	In general, “a medical laboratory shall examine specimens only at the request of a licensed physician or other person authorized by law to use the findings of laboratory examinations. However, a medical laboratory may examine specimens without a physician referral for a limited number of laboratory services to be determined by rules adopted by the department.” These services include tests for (a) glucose for patients who have been previously diagnosed as having diabetes; (b) pregnancy; (c) colon cancer; and (d) cholesterol. <sup>1</sup> An official at the Maine CLIA Program confirmed that DTC testing is limited.
<b>Maryland</b>	Limited	Md. Health Gen. Code § 17-202.1 COMAR 10.10.01.03 COMAR 10.10.06.02 COMAR 10.10.06.04 COMAR 10.10.06.12	In general, tests can be ordered only by authorized persons listed in the statute, which does not include consumers, and results must be reported directly to the ordering individuals. Certain specified “health awareness tests” (tests approved by the Secretary to be performed at a temporary laboratory), such as cholesterol tests, may be provided DTC. An official at the Maryland Department of Health & Mental Hygiene confirmed that DTC testing is limited.
<b>Massachusetts</b>	Limited	Mass. Gen. Laws ch. 111D, §§ 4,8 105 CMR 180.010 105 CMR 180.043 105 CMR 180.280 105.CMR.180.290	In general, tests may be ordered only by physicians or other authorized persons listed in the statute, and test results may be reported only to the authorized person who requested the test, unless the authorized person requests that the result be sent to the patient. The law provides an exception for tests conducted pursuant to “health promotion screening

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			programs,” for the purpose of “promoting health awareness and education among the general public by early detection of disease and/or associated risk factors.” Health promotion screening tests are “not used for the purpose of providing clinical diagnosis or treatment to patients.” A state official at the Massachusetts Department of Health and Human Services explained that such exceptions are limited to eight tests, including for pregnancy and cholesterol. <sup>1</sup>
<b>Michigan</b>	No	Mich. Comp. Laws § 333.17001 (1) (f) Mich. Comp. Laws § 333.17020 (1)	The law defines the “practice of medicine” to include “diagnosis ...by diagnostic test.” Another law that requires informed consent for genetic testing refers to “a physician or an individual to whom the physician has delegated authority.” According to an official with the Michigan Department of Community Health, DTC testing is prohibited because ordering tests and receiving results is part of the practice of medicine. However, the official stated that the prohibition does not apply to tests that are categorized as waived under CLIA.
<b>Minnesota</b>	Yes	None identified	State law is silent on the issue. An official with the Minnesota Department of Health confirmed that there are no state limitations on DTC testing.
<b>Mississippi</b>	Yes	None identified	State law is silent on the issue. An official with the Mississippi Department of Public Health confirmed that there are no state licensure regulations for clinical laboratory testing.
<b>Missouri</b>	Yes	None identified	State law is silent on the issue. An official with the Missouri Department of Health and Senior Services confirmed that DTC testing is permitted.
<b>Montana</b>	Yes	None identified	State law is silent on the issue. An official with the Montana CLIA program confirmed that DTC testing is permitted.



## Survey of Direct-To-Consumer Testing Statutes and Regulations

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Nebraska	Yes	R.R.S. Neb. § 71-1,104.01	State law is silent on the issue. An official with the Nebraska State Health & Human Services Program confirmed that DTC is permitted. However, a statute that relates to genetic testing states that a physician, or person to whom a physician has delegated authority “shall not order a predictive genetic test” without first fulfilling informed consent requirements. The state official explained that a physician has an obligation to make sure that the patient is informed before he orders a predictive genetic test, but if the patient takes it upon himself to order the test, whether directly from a laboratory or through an intermediary, informed consent is not required.
Nevada	Limited	Nev. Rev. Stat. Ann. § 652.190	In general, a laboratory may examine specimens only at the request of a licensed physician or any other person authorized by law to use the findings of laboratory tests and examinations. However, if the examination can be made with a testing device or kit which is approved by the Food and Drug Administration for use in the home and which is available to the public without a prescription, the laboratory may examine the specimen at the request of any person. In general, the laboratory may report the results of the examination only to: (a) the person requesting the test or procedure; (b) a provider of health care who is treating or providing assistance in the treatment of the patient; (c) a provider of health care to whom the patient has been referred; and (d) the patient for whom the testing or procedure was performed. An official at the Nevada State Health Division confirmed that DTC testing is limited.
New Hampshire	No	N.H. Admin. Rules He-P 817.15(a).	Regulations provide that laboratories may perform testing only at the “request of a

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			physician, dentist, chiropractor, court of law or any other person authorized by state statute to order and receive laboratory tests.” An official with the New Hampshire CLIA program stated that the rules indirectly limit the ordering of tests to licensed practitioners, but that individuals have the right to access all their medical records including laboratory test results directly from the laboratory performing the test.
<b>New Jersey</b>	Limited	N.J. Stat. Ann. § 45:9-42.42 N.J.A.C. § 8:44-2.2 N.J.A.C. § 8:44-2.7	In general, tests may be ordered only by a “licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and shall report only to those authorized by law to receive such results,” although patients can also request copy. According to an official at the New Jersey Department of Health, the only tests that are exempt are original CLIA-waived tests, such as dipstick urinalysis, fecal occult, and pregnancy tests. <sup>1</sup>
<b>New Mexico</b>	Yes	None identified	State law is silent on the issue. An official with the New Mexico state CLIA program confirmed that there are no state laws prohibiting DTC testing.
<b>New York</b>	Limited	N.Y. Pub Health Law § 576-b N.Y. Pub. Health Law § 577 10 NYCRR § 19.1(j) 10 NYCRR § 58-1.7 10 NYCRR § 58-1.8 10 NYCRR § 63.3(e)	In general, tests may be ordered only by licensed physicians “or other persons authorized by law to use the findings of laboratory examinations in their practice or the performance of their official duties.” Consumers are not listed among those authorized. Test results cannot be sent directly to patients except with written consent of the physician or authorized person, except blood type and RH factor can be given in writing to the patient without written consent. DTC testing is permitted for tests that have been approved by the Food and Drug Administration for direct, over-the-counter sale

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			to consumers. An official with the New York State Department of Health confirmed that DTC testing is not permitted, other than for certain tests relating to the blood supply, such as HIV and Hepatitis C tests.
<b>North Carolina</b>	Yes	N.C. Gen. Stat. § 130A-148 N.C. Admin. Code tit. 10A, chapter 42	With the exception of HIV tests, which can be ordered only by licensed physicians, state law is silent regarding DTC testing. An official with the North Carolina CLIA program confirmed that other than HIV tests, physicians' orders are not required.
<b>North Dakota</b>	Yes	None identified	State law is silent on the issue. An official with the North Dakota Department of Health stated that laboratory testing facilities should establish their own policies to address DTC testing.
<b>Ohio</b>	Yes	None identified	State law is silent on DTC testing, other than a law specifically allowing individuals to request an HIV test from a public health clinic. Under scope of practice laws specific to each profession, there are limitations as to what kinds of tests practitioners can order, but these laws do not explicitly prohibit individuals from requesting a test from a lab. According to an official at the Ohio Department of Health, The Ohio Medical Board has objected to stores selling "doc in a box" testing kits, but so far no laws or rules have been passed to prevent it. Nevertheless, the official stated that there is some ambiguity in the law, as well as in a 1980 Medical Board opinion possibly implying a limitation on DTC tests.
<b>Oklahoma</b>	Yes	None identified	State law is silent on the issue. An official with the Oklahoma State Department of Health stated that she was aware of no state law prohibiting DTC testing.
<b>Oregon</b>	Limited	Or. Rev. Stat. § 438.430 Or. Admin. R. 333-024-0050 Or. Admin. R. 333-024-0375	In general, tests may be ordered only by "physician, dentist, or other person authorized by law to use the findings of laboratory

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
		Or. Admin. R. 333-024-0395	examinations.” The phrase “other person authorized...” has been interpreted by several practitioner boards to include different types of licensed practitioners, but not consumers. Regulations require written consent of physicians or other authorized persons to report test results to patients. DTC testing is permitted for certain specified tests including substance abuse testing, hemoglobin, glucose, fecal occult blood, pregnancy, and cholesterol. An official at the Oregon State Public Health Laboratory confirmed that DTC testing is limited in Oregon.
<b>Pennsylvania</b>	No	28 Pa. Code § 5.41 28 Pa. Code § 5.47	Tests may be ordered only by licensed “member[s] of the healing arts” or “other persons authorized by statute” and results may be sent only to the person ordering the test. An official at the Pennsylvania Department of Health confirmed that DTC testing is not permitted in Pennsylvania.
<b>Rhode Island</b>	No	Rules and Regulations for Licensing Clinical Laboratories and Stations R-23-16.2-C&S/Lab, §1.2 R-23-16.2-C&S/Lab, §10.2 R-23-16.2-C&S/Lab, §13.2	Tests may be ordered only by licensed physicians or other authorized personnel, defined as “health professionals working under the auspices of a physician or other licensed health care professional acting within his/her scope of practice.” Patients may only have direct access to their laboratory results with written permission from their physician. An official at the Rhode Island Department of Health confirmed that DTC testing is not permitted in Rhode Island.
<b>South Carolina</b>	No	None identified	No laws specifically address DTC testing by consumers. However, an official with the South Carolina Department of Health & Environment Control stated that it is understood in South Carolina that patients cannot directly order laboratory tests. Under CLIA, “The laboratory must have a written or electronic request for patient testing from an

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			authorized person... Authorized person means an individual authorized under State law to order tests or receive test results, or both.” There is no law or rule in South Carolina listing who “authorized persons” are, but in practice laboratories have not accepted orders from individual consumers.
<b>South Dakota</b>	Yes	None identified	State law is silent on the issue. An official with the South Dakota Department of Health stated that she was aware of no state law prohibiting DTC testing.
<b>Tennessee</b>	No	Tenn. Code Ann. § 68-29-121	According to the Tennessee Code, “No person, except patients who are performing tests on themselves by order of their physician, shall examine human specimens without the written request of a physician or . . . other health care professional legally permitted to submit to a medical laboratory a written request for tests appropriate to that professional’s practice, or the written request of a law enforcement officer . . . .” Test results “shall be reported directly to the physician... or other health care professional who requested it.”
<b>Texas</b>	Yes	None identified	State law is silent on the issue. A state official at the Texas Board of Medical Examiners confirmed that as far as he knew, there were no state limitations on DTC testing.
<b>Utah</b>	Yes	None identified	State law is silent on the issue. An official with the Utah Department of Health stated that she was aware of no law prohibiting DTC testing and that there was an internal legal opinion stating that ordering a test, performing the test, and giving the results of that test to a person does not constitute the “practice of medicine.”
<b>Vermont</b>	Yes	None identified	State law is silent on the issue. An official with the Vermont Department of Health stated that Vermont has no laws or regulations addressing DTC testing or regarding who is

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			authorized to request testing or receive test results.
<b>Virginia</b>	Yes	Va. Code Ann. § 8.01-581.18:1	State law provides that when lab tests are conducted at the request of someone other than a physician, the laboratory report to the patient must state in bold type that the patient has the responsibility to contact a physician for test consultation and interpretation. An official at the Virginia Department of Health confirmed that DTC testing is allowed, and noted that the Virginia General Assembly had just passed a new law, which will become effective July 1, 2007, that allows physicians to request that laboratories send physician-ordered test results directly to patients. The law provides immunity to physicians for failing to act on the results of a laboratory test if the test is not requested or authorized by them, other than in limited situations such as when the results are provided to the physician by the person tested with a request for consultation.
<b>Washington</b>	Yes	Wash. Admin. Code § 246-338-010 Wash. Admin. Code § 246.338-070	State law provides that “test reports must... be released only to the “authorized persons or designees” and defines “authorized person” as “any individual allowed by Washington state law or rule to order tests or receive test results.” An official with the Washington State Department of Health stated that nothing in Washington State law prohibits DTC testing.
<b>West Virginia</b>	Yes	None identified	State law is silent on the issue. An official at the West Virginia Department of Health confirmed that state law does not prohibit DTC testing.
<b>Wisconsin</b>	Yes	Wis. Adm. Code HSS 165.16 Wis. Adm. Code HSS 165.17	Law provides that clinical laboratories “shall examine specimens only at the request of persons or agencies authorized or allowed by law to submit specimens” and “shall report

## Survey of Direct-To-Consumer Testing Statutes and Regulations

Jurisdiction	DTC Permitted?	Citation to Statute or Regulation	Comments
			specimen findings to persons authorized or allowed by law to receive such reports.” However, an official with the Wisconsin CLIA program stated that Wisconsin does not have any regulations that would prohibit DTC testing; she stated that the cited provision no longer applies to clinical labs.
Wyoming	No	Wyo. Stat. § 33-34-107 Wyo. Stat. § 33-34-108	Tests may be ordered only by a physician, dentist, “or other persons authorized by law to use the findings of laboratory examinations.” Test results may be reported only “to or as directed” by the person who ordered the test. An official at the Wyoming Office of Healthcare Licensing and Surveys confirmed that DTC testing is not permitted.

### Scope and Methodology

This chart was compiled based on a survey of state statutes and regulations and state government officials in order to determine whether state law permits direct ordering of laboratory tests by consumers and the delivery of test results from clinical laboratories directly to consumers. Federal regulations governing clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which is implemented through a CLIA program in each state, leave the decision regarding the permissibility of direct to consumer (DTC) testing up to state law. Federal regulations require the laboratory to have a “written or electronic request for patient testing from an authorized person” (42 C.F.R. § 1241(a)). However, the regulations do not define “authorized person.” Thus it is up to each state to determine who is an authorized person.

In order to determine whether individual states permit DTC testing, individuals listed as the state CLIA representative were contacted and asked whether state law permitted direct ordering of tests by consumers from laboratories and direct delivery of test results to consumers by laboratories. Traditional LEXIS research of state statutes and regulations, attorney general opinions, and in some instances case law, was also undertaken using a variety of search terms. Some state web pages were searched if a government representative suggested it or if other avenues did not yield information.

The search strategy EXCLUDED laws and regulations related to newborn screening, DNA testing for criminal justice purposes, specific health care facilities such as hospitals and outpatient facilities, genetic discrimination, reportable diseases, reimbursement, paternity testing, non-diagnostic testing generally, or waived testing (although some information regarding waived testing was obtained).

Column 2 of the chart (“DTC permitted?”) reflects a synthesis of both state statutes and regulations and the opinions of state government officials. In cases where the law is ambiguous, the state official’s view was considered to be the final answer; thus states with very similar statutory or regulatory

## **Survey of Direct-To-Consumer Testing Statutes and Regulations**

provisions may nevertheless have different policies. Where no relevant statutory or regulatory provisions were found, and no response was obtained from a state official, the conclusion drawn was that DTC is permitted. This conclusion is justified by the fact that if state law does not define “authorized person” all persons are presumed to be authorized.

Thanks to Elena Cohen for her assistance in preparing this chart.

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<sup>1</sup> These states explicitly exempt certain entities from restrictions on DTC testing. These entities may include laboratories operated by the United States government, public health laboratories, and laboratories maintained exclusively for research and teaching purposes that do not involve patient or public health service.