

special report

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Now 43 states offer
Direct Access Testing

25 Percent More States Allow Direct Access Testing

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- ▶ The number of states allowing direct access testing has increased substantially in the last 2 years.
- ▶ Several states may expand the list of direct access tests due to new legislation or regulation.
- ▶ In states where direct access testing is not permitted, services are often available by other means.
- ▶ As laboratories establish their own policies in regard to direct access testing, they should be aware of their state laws.

In the June 1999 edition of *Laboratory Medicine* [Vol. 30, No. 6], the ASCP Washington Office wrote an article on direct access, or patient authorized, testing. Because of the significant interest expressed by ASCP members, the public, and the press, the ASCP Washington Office has revisited this issue to provide you with additional and updated information on the topic. The accompanying chart [F1] is a compilation of state (plus Puerto Rico and Washington DC) responses gathered during August and September 2001 interviews on direct access testing.

As it turns out, there have been some interesting changes since our 1999 article. The re-examination has uncovered that a number of states that previously identified themselves as either not permitting direct access testing or unsure of the legality of such testing, now indicate they allow it. These states include Arkansas, Illinois, Louisiana, Minnesota, Montana, Nebraska, Oklahoma, Puerto Rico, and Washington DC. The ASCP Washington Office's research has determined that

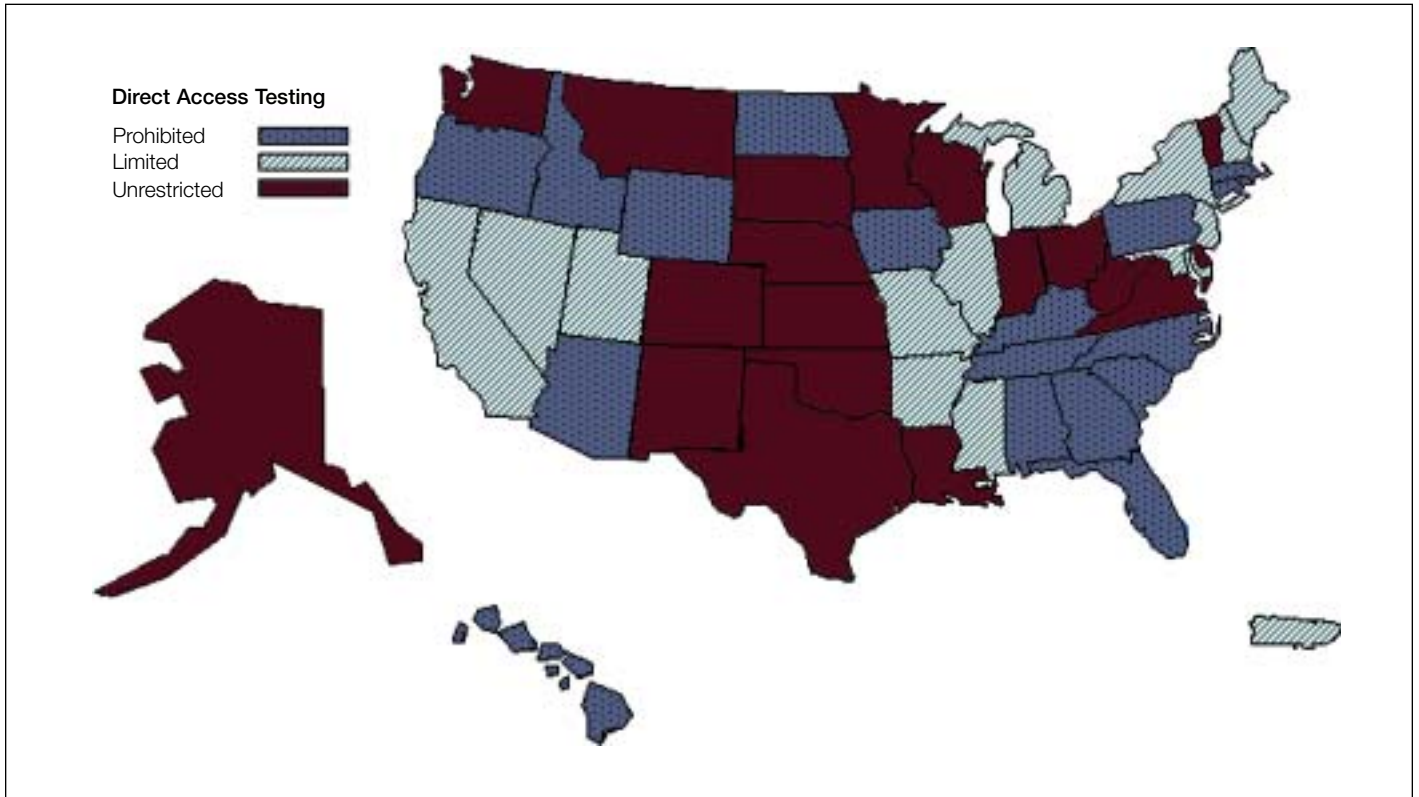
34 states allow direct access testing and 18 prohibit it. This is a substantial change from our 1999 study, which found that 27 states allowed such access.

We note that some states are in the process of expanding to patients direct authority to order laboratory testing services. Beginning in 2002, California will expand its list of direct access tests to include all tests that are approved by the federal Food and Drug Administration for over-the-counter sale without a prescription. Currently, California allows direct access testing for glucose, cholesterol, pregnancy, occult blood, and HIV (FDA-approved home-based blood collection kits only). This change came about as a result of the enactment of SB 1131, which was introduced by Senator Michael J. Machado (D-Sacramento) and signed into law by Governor Gray Davis on July 18, 2001. Similar legislation is currently being considered in the New York General Assembly.

Only a few of the states allowing direct access testing specify in-state law that patients can obtain laboratory test services without a medical order. Maine, for example, allows direct access testing for glucose, cholesterol, urine pregnancy, and fecal occult blood. Other states, such as Illinois, Michigan, and New Jersey, allow waived tests to be provided via direct access. However, most of the states allowing direct access testing do so because their law is silent on the issue of whether patients may authorize laboratory testing for themselves.

In such cases, the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 provide the answer. According to the Centers for Medicare and Medicaid Services (formally the Health Care Financing Administration), in the absence of any state law prohibiting patient authorized testing, such testing is not prohibited by CLIA of 1988. The de-

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[F1] Visual representation of state-by-state policies regarding direct access testing. Of the 50 states plus Washington DC and Puerto Rico, 34 allow for direct access testing in 2001. This is an increase of 7 states since a similar survey taken in 1999.

cision to provide direct access testing in these states falls to each laboratory.

In states where direct access testing is not permitted, testing services may be provided by other means. For example, public health screening programs may allow laboratories to offer testing services without a medical order. In Oregon, public health screening program allows for glucose, cholesterol, and urine pregnancy testing. Standing orders may also be used to allow individuals to obtain testing services. Some states, such as New York, are very restrictive with regard to standing orders, requiring that the order be specific to the individual and analyte tested and that it provide testing authority for no more than 6 months. Other states allow standing orders to cover multiple patients, and that they remain in effect for a year or more.

Some states have also considered liability issues related to direct access testing. In Virginia, regulations have been adopted that specify it is the responsibility of the patient to obtain a diagnosis from the laboratory test. Other states caution that while there may be no prohibition on providing test services without a medical order, laboratory staff may not be allowed to interpret the test results or provide a diagnosis for the patient as this could be construed as an unauthorized practice of medicine. This policy is not universal. The state of Washington does not prohibit laboratories from interpreting laboratory test results.

T1 explains, state-by-state, whether there are any limits on the types of laboratory tests that may be provided directly to patients. Some states, for example, permit direct access testing at independent laboratories but prohibit it at hospitals, as is the case in Arkansas and Mississippi (Missouri prohibits direct access testing of in-patients only). In states where direct access is permitted, laboratories are advised to establish their own policies with regard to direct access testing. State officials warn that if a facility is not following its policies, a citation against the facility may be issued.

ASCP notes that this information comes from interviews with state health officials and should not be construed as a binding legal opinion on the state. Laboratories seeking to perform testing without a physician's order may wish to obtain verification from their state health department officials prior to providing direct access testing.

For Further Information on Direct Access Testing

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Summary of Direct Access Testing by State

State	Direct Access Testing Permitted	Limitations on Direct Access Testing (DAT)	Notes
Alaska	Yes	No limits	State law doesn't prohibit direct access testing.
Alabama	No	DAT prohibited	
Arizona	No	DAT prohibited	
Arkansas	Yes	See Notes	Hospital laboratories may not perform direct access testing, but other laboratories are not similarly restricted.
California	Yes	Limited	California current allows glucose, cholesterol, pregnancy, occult blood and HIV (FDA-approved home collection kit only) to be provided via direct access testing. Beginning on January 1, 2002, the state will also allow all tests approved by the federal Food and Drug Administration for over-the-counter use without a prescription to be provided as direct access tests.
Colorado	Yes	No limits	State law doesn't prohibit direct access testing.
Connecticut	No	DAT prohibited	
Delaware	Yes	No limits	State law doesn't prohibit direct access testing.
District of Columbia	Yes	No limits	State law doesn't prohibit direct access testing.
Florida	No	DAT prohibited	State law does allow for use of FDA-approved home-based HIV collection kits.
Georgia	No	DAT prohibited	
Hawaii	No	DAT prohibited	
Idaho	No	DAT prohibited	
Illinois	Yes	Limited	Only tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) may be self-authorized.
Indiana	Yes	No limits	State law doesn't prohibit direct access testing.
Iowa	No	DAT prohibited	
Kansas	Yes	No limits	While Kansas does not prohibit direct access testing, hospital laboratories are required to specify who may authorize laboratory testing.
Kentucky	No	DAT prohibited	
Louisiana	Yes	No limits	State law doesn't prohibit direct access testing.
Maine	Yes	Limited	Maine allows self-authorization for glucose (provided the individual is a diagnosed diabetic), cholesterol (total and HDL), urine pregnancy, and fecal occult blood.
Maryland	Yes	Limited	Maryland allows direct access testing for cholesterol (total cholesterol and HDL only). The laboratory must be licensed to perform testing if it provides testing services without a medical order.
Massachusetts	No	DAT prohibited	
Michigan	Yes	Limited	Only tests classified as waived under CLIA may be self-authorized.
Minnesota	Yes	No limits	State law doesn't prohibit direct access testing.
Mississippi	Yes	Hospitals: DAT prohibited. Other Laboratories: No limits	Hospital-based laboratories may not perform direct access testing, but state law does not prohibit other laboratories from performing direct access testing.
Missouri	Yes	Limited	Hospitals may not perform direct access testing on in-patients. Otherwise, there are no restrictions on the types of tests that be performed via direct access.

Summary of Direct Access Testing by State

State	Direct Access Testing Permitted	Limitations on Direct Access Testing (DAT)	Notes
Montana	Yes	No limits	State law doesn't prohibit direct access testing.
Nebraska	Yes	No limits	State law doesn't prohibit direct access testing.
Nevada	Yes	Limited	Nevada permits direct access testing only in cases where the test may be performed with a testing device or kit approved by the FDA for use in the home that is available to the public without a prescription.
New Hampshire	Yes	No limits	State law doesn't prohibit direct access testing.
New Jersey	Yes	Limited	Only tests classified as waived under CLIA may be self-authorized.
New Mexico	Yes	No limits	State law doesn't prohibit direct access testing.
New York	Yes	Limited	Only ABO blood grouping and Rh typing may be provided as direct access testing.
North Carolina	No	DAT prohibited	
North Dakota	No	DAT prohibited	
Ohio	Yes	No limits	State law does not prohibit direct access testing; however laboratory must be state certified if performing testing for sexually transmitted diseases.
Oklahoma	Yes	No limits	State law doesn't prohibit direct access testing.
Oregon	No	DAT prohibited	
Pennsylvania	No	DAT prohibited	
Puerto Rico	Yes	Limited	Puerto Rico does not allow hospitals to perform direct access testing, but independent laboratories may perform via direct access those laboratory tests that are approved by the federal Food and Drug Administration for over-the-counter use.
Rhode Island	No	DAT prohibited	
South Carolina	No	DAT prohibited	
South Dakota	Yes	No limits	State law doesn't prohibit direct access testing.
Tennessee	No	DAT prohibited	
Texas	Yes	No limits	State law doesn't prohibit direct access testing.
Utah	Yes	Limited	State law limits direct access testing performed at hospital-based laboratories to those tests that can be understood by the patient. It is unclear whether this restriction applies to other laboratories.
Vermont	Yes	No limits	State law doesn't prohibit direct access testing.
Virginia	Yes	No limits	State law doesn't prohibit direct access testing.
Washington	Yes	No limits	
West Virginia	Yes	No limits	State law does not prohibit direct access testing; however, HIV testing may require physician's order.
Wisconsin	Yes	No limits	State law doesn't prohibit direct access testing.
Wyoming	No	DAT prohibited	

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, establishing quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed.

View the current CLIA regulations online
<http://www.phppo.cdc.gov/clia/regs/toc.asp>