ASCP **STRONGER**TOGETHER

Policy Statement

Direct Access Testing

(Policy Number 01-02)

Policy Statement

In order to ensure optimal patient health outcomes, ASCP believes that patients choosing direct access testing (DAT) should select a CLIA certified laboratory and review all results with their physician.

Background and Rationale

I. Introduction

Direct access testing is becoming an increasingly popular option for patients wishing to monitor their health status and make more decisions about their own health care. DAT can be a useful tool in enhancing the doctor/patient relationship. ASCP believes it is critical for patients to use reliable testing sites, consult with their physician, and pursue appropriate follow-up treatment.

DAT presents a myriad of issues for patients, clinical laboratories, physicians and insurance companies. These issues include, but are not limited to, (A) medical implications including patient understanding of test results, (B) the legal implications and liability issue of DATs, as well as (C) issues involving reimbursement.

II. Medical, Legal and Payment Issues

A variety of medical, legal and payment issues are associated with DAT including the following:

A. Medical Issues

While DAT has the potential to benefit some patients, it may not be appropriate for all individuals, as it has the potential to have a negative impact on health status. Direct access testing may be beneficial for some individuals. Patients are able to have greater access to tests without dealing directly with physicians or with complex managed care situations. DAT also

allows patients to keep certain sensitive test results, such as drug tests or tests for sexually transmitted diseases, out of their medical records or away from potential insurers.[1] However, if the patient's physician is unaware of such problems, he or she cannot provide care for those conditions.

One group that finds DAT particularly appealing has come to be known as the "worried well." These individuals are typically baby-boomer age, highly educated, and want to be more involved in monitoring their own health care status.[2] At a recent meeting the Clinical Laboratory Improvement Advisory Committee (CLIAC) considered a variety of viewpoints on the issue of DAT. During the presentation on physician's views, concerns were expressed about the high costs associated with repeated, unnecessary testing for the worried well as well as their ability to handle "bad" results without the immediate attention of a physician.[3] Thus, depending on the tests ordered, it may be necessary for the DAT laboratory to provide counseling or referral for patients choosing DAT.

1. Interpreting/Understanding Test Results
   To ensure that patients understand the results of their direct access tests, laboratories performing DAT should provide patients undergoing testing with easy to comprehend test results.[4] In fact, some states require that the laboratory director be responsible for providing a clear explanation of the results to the patient.*

   It can be beneficial for laboratories to make available to the patient, pre-testing information (e.g., the need for fasting, eating or drinking, effect of specific medications, etc.) that may affect test results. If patients are simply given their results and a range of numbers to understand the results, there may be both increased false-negatives and false-positives in test result interpretation.

   There is concern among the medical community that tests are being conducted to screen for certain conditions (e.g., expensive total body scans to screen for cancer, a cheek swab test to screen for cystic fibrosis DNA, or an inexpensive cholesterol test that does not screen for triglycerides, an important marker for heart disease risk) in DAT laboratories that would not normally be ordered by a physician. The concern here is that DAT could result in false-positives or false-negatives, possibly leading to increased health care costs as well as adverse impacts on patient health.[5]

2. Consultations
   For optimum patient health outcomes, ASCP recommends that patients consult with their physician for proper interpretation of test results. Laboratory testing helps better identify a patient's health status. Clinicians may have access to the patient's family history and other data that can critically affect test interpretation and can order additional tests to clarify the results or predict risk.[6]

B. Legal Issues

Laws and regulations regarding DAT vary by state, therefore each laboratory performing DAT must operate in accordance with federal and state law. The federal law impacting laboratory testing is the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Although state laws vary, states regulate DAT under one of three basic approaches: states may prohibit DAT entirely, allow DAT in certain situations, or allow DAT without restriction.

1. Federal Law
   CLIA does not expressly define who can "order or receive" a laboratory test.[7] Rather, it reserves this authority to the states. According to a Centers for Medicaid and Medicare Services (CMS) interpretation of CLIA, if a state does not prohibit a patient from ordering or receiving laboratory tests, CLIA would not bar an individual from obtaining testing.[8] Thus, in such states DAT would be legal. Clinical laboratories are not required to allow DAT, however, laboratories would need to establish policy as to whether it would provide DAT and which tests, if any, it would provide.

2. State Law
   One study found 34 states allow direct access testing in some form.[9] In 20 of these states there are no limitations on DAT, because there are no laws limiting patient ordered testing.** The remaining 14 states have limitations on the types of DAT allowed.*** Since this study was published one additional state, Arizona, has changed its legislation

* The state of California Health and Safety Code section 123147 states that "a patient's clinical laboratory test results be conveyed in plain language and in oral, written, or electronic form."

** These 20 states are: Alaska, Colorado, Delaware, District of Columbia, Indiana, Louisiana, Minnesota, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, South Dakota, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

*** These 14 states are: Arkansas, California, Illinois, Kansas, Maine, Maryland, Michigan, Mississippi, Missouri, Nevada, New Jersey, New York, Puerto Rico, and Utah.

to allow for limited direct access testing.[10] These limits involve restricting the types of test that may be ordered via direct access. Several states allow for direct access only for tests classified as waived under CLIA.

Physician's standing orders may also be used to allow testing services through consultation with a doctor. Patients may also be able to obtain laboratory testing by calling a laboratory staffed by a physician who then orders the test.[11] Some states may also have laws regarding the readability of laboratory test results, requiring the results to be provided to patients in clear, easy to understand language.

3. Liability
   When patients order their own tests, it is important that the laboratory performing the tests has a strong patient communication and result reporting system. State laws vary on who holds the burden of legal responsibility when it comes to communicating the results of direct access testing. Most states may hold the laboratory director or the patient's physician legally responsible, if the results are sent to that physician. At least one state law holds the patient responsible.[9] Making sure an important result is effectively communicated in the DAT setting is more complex than the usual situation of physician ordered tests, where reporting lines are more routine and established.

C. Payment Issues

Because a majority of insurance providers as well as Medicare and Medicaid will not pay for laboratory testing without a physician's order, patients seeking testing must pay for testing fees. ASCP believes that laboratories providing DAT should inform patients about possible restrictions in insurance coverage for tests that are not ordered by a physician prior to providing these services to patients.

III. Recommendations

To ensure the highest quality of patient health, ASCP recommends the following regarding direct access testing:

- Laboratories should follow applicable state laws regarding direct access testing.
- Laboratories should inform patients about restrictions in insurance and medical coverage.
- Laboratories should make information available that could have an effect on test results.
- Laboratories should provide easy to interpret test results.
- Patients should consult with their primary care physician when ever possible after receiving DAT test results.
- States considering legislation on DAT should establish a commission of clinicians and pathologists to closely examine medical and legal issues.

IV. Conclusion

ASCP believes that it is important for physicians and patients to use the test results as a mechanism to discuss a variety of health-related issues and future laboratory testing needs. It is essential that patients who chose to engage in direct access testing select a CLIA certified laboratory and have their test results reviewed by their primary care physician.

References

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