

POSITION STATEMENT

Direct-to-Consumer Laboratory Testing

July 2015

Introduction

Direct-to-consumer (DTC) laboratory testing, also known as direct access testing, permits consumers to order laboratory tests directly from a laboratory without necessarily having to work with their healthcare provider. These test results may be used to monitor an existing health condition, identify a previously unknown medical disorder, or provide data regarding personal health characteristics. DTC laboratory testing is a key element of ongoing efforts to increase individuals' engagement in managing their healthcare, and it is critical that DTC test results are accurate and well understood. Laboratory professionals play a vital role in this process.

Background

Government Oversight of DTC Laboratory Testing

DTC laboratory testing in the U.S. is regulated at both the federal and state levels. On the federal level, the Food and Drug Administration (FDA) reviews the test kits and medical claims before a commercial in vitro diagnostic (IVD) product can be placed on the market to help ensure safety and efficacy; the Centers for Medicare and Medicaid Services (CMS) helps to ensure the quality and accuracy of the laboratories performing these commercial tests and laboratory developed tests through inspections and oversight of laboratory performance with proficiency testing; and the Federal Trade Commission (FTC) investigates deceptive marketing practices and false claims. Ultimately, the states determine whether a consumer can order a laboratory test directly, without going through a healthcare provider.

ACC POSITION:

AACC supports expanding consumer access to DTC laboratory testing services that have demonstrated analytical and clinical validity and clinical utility. It is important that individuals learn more about their health status so they can become more involved in decisions affecting their well-being. AACC recommends that only CLIA-certified laboratories perform DTC testing and that such facilities provide consumers sufficient information and/or access to expert help to assist them in ordering and interpreting tests. Consumers should work with qualified healthcare providers in making decisions affecting their personal health.

Consumer Access to Laboratory Testing

In recent years, a paradigm shift has taken place with consumers seeking greater involvement in decisions affecting their healthcare and with policies that enable this involvement, providing individuals more control over their personal health information. Laboratory test results are an integral component of health information, and in the past, state laws limited the ordering of laboratory tests to physicians. Currently, 37 states and the District of Columbia permit consumers to order some or all of their laboratory tests directly—without the involvement of a physician (1). Similarly, the federal government joined this trend by issuing a regulation directing clinical laboratories to provide individuals with access to their test data upon request (2). With these new policies in place, consumers are increasingly involved in guiding the health decisions that affect their lives.

Changing Healthcare Delivery System

In the past, individuals had to visit a healthcare facility—a physician’s office, hospital, or clinical laboratory—to have blood or other specimens collected for clinical testing, and they had to wait a period of days to weeks for a call from their doctor with the results. Many more options exist for today’s consumers. Individuals now can buy over-the-counter test kits that allow them to collect a sample and mail it to a laboratory that performs the test, or, in some cases, conduct the test themselves in their own homes. Consumers can also identify, order and buy laboratory services directly in a variety of convenient non-traditional settings, such as retail centers, pharmacies, mobile testing facilities, and wellness centers. These options provide individuals with immediate access to timely services and results.

Considerations

DTC laboratory testing can provide valuable information to individuals about their health status in a timely and convenient manner. However, many healthcare providers and policymakers are concerned that some DTC laboratory tests may be of questionable quality and value, particularly those offered in non-traditional settings. In addition, questions have arisen about whether consumers have enough background knowledge and information to make sound decisions based on their test results (3). Consumers might not understand the limitations associated with some tests nor do they necessarily have the knowledge to interpret the tests without input from healthcare professionals. Over the past decade policymakers have been struggling to balance these concerns with a growing desire of individuals to take a more active role in making decisions affecting their health.

Testing Quality and Marketing Practices

Regulations require that laboratory testing be performed by educated, well-trained and experienced laboratory professionals. Such requirements help ensure that testing is of high quality and provides valuable information to clinicians and patients. DTC testing sites that meet regulatory requirements and employ qualified individuals can provide quality testing services in an efficient way. However, some testing facilities

have claimed exemption from regulatory oversight asserting they provide “health information” not diagnostic test results (4). As consumer-driven testing has expanded to non-traditional laboratory sites, concerns have been raised about the quality of the testing and the credentials of the personnel performing the tests (3).

A 2010 Government Accountability Office (GAO) investigative study of four DTC entities re-enforced this concern when it reported widespread “deceptive marketing” among the companies and that the test results were “of little or no practical use” (5). An earlier 2006 GAO investigative study on nutrigenetic testing showed similar findings, stating that the reviewed tests “mislead consumers by making predictions that are medically unproven” and the information was meaningless (4). Many stakeholders, including the Secretary’s Advisory Committee on Genetics, Health, and Society, have urged greater consumer education regarding the risks and benefits of DTC testing (6).

Consumer Costs and Risks

With nearly 40 states granting consumers direct access to clinical testing, the cost to consumers and potential health risks must be considered. Self-directed laboratory testing is not covered by health insurance; insurers generally pay only for tests ordered under the authorization of a physician, a practice that is not likely to change in the near future. Also, the price for a test or panel of tests may vary by laboratory. Consumers need to be fully informed in advance of the costs associated with tests.

Beyond cost, health risks are an even greater consideration. Poor outcomes of DTC testing can result when the test is of poor quality, if it is conducted inappropriately, or if a consumer misinterprets a result and bases a healthcare decision on this misinterpretation. Even when direct access is limited by state law to a narrow menu of general health tests, such as cholesterol and prostate specific antigen (PSA) testing, risk is inherent in the process. For example, concern has arisen that some patients may stop taking a medication or change its dosage based on DTC test data, while others might institute or continue an unhealthy lifestyle (7). Despite a lack of evidence in the scientific literature that this does indeed happen, such inadvisable action by consumers

could lead to negative impacts on health. Unless DTC tests have been fully proven and healthcare decisions based on the results are clear-cut, it will be important for consumers to consult with a qualified healthcare practitioner to select the appropriate test and interpret the results.

Test Reporting and Interpretation

Laboratory reports have been developed to provide specific information to highly trained and knowledgeable healthcare providers. As such, the reports typically provide a numeric value and a reference interval, and may also include a brief description of the result. This minimal information, when considered with all other factors such as any symptoms of disease that may be present, is sufficient for healthcare professionals to make clinical decisions. An individual consumer likely will need far greater context to fully understand the meaning of the test and to determine next steps. For example, an abnormal test result outside the reference interval may or may not indicate an underlying health problem (3). Alternatively, an individual may be falsely reassured by a test result in the normal range even when signs and symptoms warrant medical attention. Finally, consumers may not understand the limitations of the tests and therefore may interpret the results of their tests incorrectly.

Laboratory professionals can play a vital role in all aspects of this consumer-driven process, including educating individuals about the benefits and limitations associated with tests and assisting in the selection of the most appropriate test for that particular person. In addition, highly trained and experienced laboratorians can assist in the interpretation of test results and can provide consumers guidance on whether additional testing is required to confirm or clarify results, directing them to medical professionals for any necessary follow-up care. Patients can also access reliable information electronically through resources such as Lab Tests Online (<https://labtestsonline.org>), which was developed and is maintained by laboratory professionals to help patients and caregivers understand the many laboratory tests that are a vital part of medical care.

Positions

AACC supports greater consumer access to their personal health information. To ensure the full benefits of DTC testing, AACC supports the following positions:

- ▶ AACC recommends that Congress and relevant federal and state agencies remain vigilant in their oversight of DTC testing facilities and ensure that policies governing DTC testing take into account the unique responsibilities of entities that market their services directly to individual consumers.
- ▶ AACC recommends that CMS ensure all DTC testing facilities are CLIA-certified.
- ▶ AACC supports FTC enforcement against DTC providers engaging in false or misleading marketing practices.
- ▶ AACC urges CMS and FDA to establish requirements for DTC providers to disclose sufficient information about their products and services so that consumers can make fully informed health decisions; such disclosures would include but not be limited to:
 - User-friendly descriptions of risks, benefits, and limitations of all tests offered;
 - Clear and understandable reports of test results, with enough information to assist in decision-making;
 - Prominent instructions to contact a qualified healthcare provider with any questions or concerns; and
 - A comprehensive, public listing of tests offered and prices charged.
- ▶ AACC recommends that the broader laboratory community collaborate with federal agencies to provide information to the public on issues of cost, benefits, interpretation and limitations of DTC tests.
- ▶ AACC encourages consumers to evaluate the test results as part of an overall health assessment with their healthcare provider.

References

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