POSITION STATEMENT

Direct-to-Consumer Laboratory Testing

October 2024

Introduction

The ability of consumers to order medical testing independently has expanded significantly in recent years. Individuals can now order tests to obtain information about an existing health condition, to identify a suspected medical disorder, or to learn about genetic and environmental factors that may affect their personal health. Consumer testing has become an important tool for individuals to manage their healthcare. Therefore, it is critical these test results are accurate and well understood. Laboratory professionals play a vital role in this process.

Background

The Changing Landscape of Laboratory Testing

Laboratory tests are typically ordered by a healthcare provider in response to a patient encounter, requiring the individual to go to a medical facility and have a sample collected (typically blood or urine) and sent to a laboratory for analysis. The laboratory performs the test, and the ordering provider interprets the results and counsels the patient regarding therapy or follow-up testing. In recent decades, technological advancements and increasing consumer interest in managing their personal health has created a market for individuals to order tests without direction from a medical provider.

ADLM POSITION:
ADLM supports expanding and encouraging consumers' ability to access their own health information by allowing individuals to directly order their own laboratory tests. Medical tests can help individuals learn more about their health and become more involved in decisions affecting their well-being when performed appropriately. Only reputable CLIA-certified laboratories should perform direct-to-consumer testing and should provide consumers with sufficient information and/or expert help to assist them in interpreting the results. Consumers should always consult qualified healthcare providers when making decisions that could affect their personal health.

Today's testing landscape offers great flexibility. Consumers can utilize over-the-counter test kits, send samples to labs, or test at home. Online platforms allow for easy selection and ordering of laboratory services. Samples can also be obtained through a variety of methods, including local collection centers, at-home services, and even mobile units (1). This versatility allows consumers to access on-demand tests ranging from wellness to personalized medicine, to infectious disease testing. Results are often quickly available online - a major attraction for consumers, but the quality can vary considerably between different tests and the labs offering them. By 2030, the global market for these tests is likely to exceed $20 billion (2).

Regulation of Laboratory Testing

Laboratory testing in the U.S. is subject to federal regulation. Clinical laboratories performing testing are overseen by the Centers for Medicare and Medicaid Services (CMS) utilizing national standards established under the Clinical Laboratory Improvement Amendments (CLIA). The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) assist CMS in this process. For example, FDA reviews commercially available test kits and their associated medical claims used in clinical laboratories to ensure the safety and efficacy of the products before they are cleared or approved for use.

CMS ensures the integrity of laboratories performing testing via inspections and consistent oversight. This scrutiny is bolstered with proficiency testing by accredited organizations. In tandem, the Federal Trade Commission (FTC) monitors for deceptive marketing strategies and unsubstantiated claims. The decision as to whether consumers can directly order a laboratory test, bypassing a healthcare provider, currently rests at the state level. While all clinical laboratories are bound by CLIA standards, there is not currently a dedicated framework for regulating collection and testing of home collected samples.

Considerations

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 tests may be of questionable quality and value, particularly those offered in non-traditional settings. In addition, questions have arisen about whether consumers will always make medically appropriate decisions based on their test results (3). Over the past several years policymakers have sought to balance these concerns with a growing desire of individuals to take a more active role in decisions affecting their health.

Testing Quality and Marketing Practices

CLIA mandates that laboratory testing be conducted by educated and skilled professionals to ensure high-quality results for clinicians and patients. However, the expansion of consumer-driven testing to non-traditional laboratories has sparked concerns about test quality and the qualifications of the staff.

Certain companies, such as some in the wellness industry argue they provide "health information," sidestepping regulatory oversight (4) Government Accountability Office studies in 2006 and 2010 highlighted deceptive marketing and unreliable test results in some of these companies, prompting calls for better consumer education (5). To safeguard consumers, stricter regulatory oversight, transparent and accurate advertising, and clear communication of test limitations are essential in the marketplace.

Potential Risk and Harm

The ability for a person to choose and order their own test assumes some basic knowledge of their body and health. Without proper guidance, uniformed individuals may misuse the tests or misinterpret the results (6). To mitigate potential harm, it is essential that labs performing consumer directed testing explain the purpose of each test in an accessible and easily understandable way. Labs should also detail when it's appropriate to use the test, potential risks, and associated costs. Results should be presented in an easy-to-understand manner and options for further professional medical advice should be available. It's crucial that the purpose of each test and its collection methods are clearly communicated to consumers. These procedures and methods need to be thoroughly checked to guarantee consistent and reliable outcomes.

Test Reporting and Interpretation

Laboratory reports are designed primarily for medical professionals who are trained to interpret the data and terminology. For the average person, understanding these results can be challenging. A result that seems unusual might not indicate a health issue, while a "normal" result doesn't exclude disease, especially if someone feels unwell (3). Laboratorians can help in these situations by using understandable language and/or graphics that illustrate the meaning and limitations of test results. Online resources developed by lab professionals can offer insights into the wide array of medical tests and their significance.

Positions

ADLM supports consumer efforts to actively engage in their own healthcare including appropriate use of clinically relevant laboratory testing. The specific roles and actions of various stakeholders in establishing best practices for such testing are outlined below.

Healthcare Providers

- Utilize convenient, cost-effective modes of testing in properly certified laboratories.
- Consult experts when assessing the quality of a laboratory and/or when questions regarding a test order or results arise.

Laboratory Service Providers

- Validate all sample collection, sample processing, and testing practices, per CLIA regulations or consistent with FDA guidance.
- Provide transparent, understandable information regarding clinical indications, specimen collection, results interpretation, and cost to consumers.
- Provide timely clinical recommendations to customers with the test results.
- Comply with privacy regulations and ensure that customer data is handled securely and confidentially. Provide clear information about data collection, storage, and sharing practices to customers.

Regulators/Policymakers

- CMS should ensure all laboratories engaged in commercial testing are CLIA certified.
- CMS and FDA should ensure that all sample collection and testing systems, even those developed for unique self-collection applications, are either FDA-approved or properly validated per CLIA.
- Regulatory agencies should establish and maintain a public formulary of clinically valid and analytically sound testing procedures.
- Regulatory agencies should ensure providers 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 tests;
    - Clear and understandable reports of test results with enough information to assist in making healthcare decisions;
    - Prominent instructions to contact a qualified healthcare provider with any questions or concerns; and
    - A comprehensive, public listing of tests offered and prices charged.
- FTC should vigorously prosecute providers that engage in misleading or fraudulent marketing and testing practices.
- The Agency for Healthcare Research and Quality (AHRQ) should encourage research into outcomes of consumer-initiated vs. conventional testing practices.

References

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