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Clinical Lab Tests Need Stronger FDA Oversight to Improve Patient Safety

Congress should authorize risk-based review of all in vitro diagnostics, including those from laboratories

Overview

In vitro diagnostics (IVDs) play an indispensable role in modern medicine. Health care providers routinely rely on these tests—which analyze samples such as blood or saliva—to help diagnose conditions and guide potentially life-altering treatment decisions. In 2017, for example, clinicians ordered blood tests during about 45% of emergency room visits in the United States, according to the Centers for Disease Control and Prevention. Diagnostics also help trace the spread of disease outbreaks and inform mitigation strategies during public health emergencies such as the COVID-19 pandemic.

However, flawed tests can lead to serious harm. If results are not accurate and reliable, patients may receive the wrong treatment for their condition or undergo unnecessary and potentially invasive procedures. They may also experience delays in diagnosis and care that allow a disease to progress to an advanced stage and, if communicable, infect more people.

The Food and Drug Administration regulates IVDs as medical devices, and its requirements for these products vary depending on the level of risk associated with the test. Higher-risk tests must meet more stringent review standards and demonstrate both clinical and analytical validity (see “Definitions”) before they can be marketed. But IVDs made and used in a single laboratory—known as lab-developed tests (LDTs)—have been largely excluded from these regulatory requirements for more than 40 years. The comparatively limited oversight of LDTs no longer reflects the risks that these tests can pose, and policymakers have debated for years how best to address this imbalance. The most recent, and most comprehensive, proposal is the Verifying Accurate, Leading-Edge In vitro clinical test Development (VALID) Act, which was introduced in March 2020.

Once a small segment of the market, LDTs now number in the tens of thousands and in some cases have become more complex and widely used, increasing the potential risk to public health. The four types of tests examined in this brief—COVID-19 tests, noninvasive prenatal testing (NIPT), direct-to-consumer (DTC) genetic testing, and companion diagnostics—illustrate these public health concerns and underscore why Congress should pass legislation to ensure that FDA’s risk-based requirements for diagnostics apply to commercial IVDs and LDTs alike. Such a unified regulatory system would improve protections for patients and public health.

Key risks associated with IVDs

If IVDs, including LDTs, are not analytically and clinically valid, these tests can pose significant risks to patients and the general public, including:

- Health effects from receiving unnecessary treatment.
- Missed treatments or delay in receiving proper treatment, which may lead to worsening of disease and more severe long-term outcomes.
- Emotional burden of being wrongly diagnosed.
- Unnecessary confirmatory testing that may be painful or invasive, such as a biopsy.
- In the case of false negatives for an infectious disease, continued spread of that disease, which could threaten public health.
- Increased financial burden on the health care system associated with misdiagnoses, wrong or delayed treatments, and worsening or prolonged disease.

Recent advances in diagnostic technology have contributed substantially to scientific understanding of disease and helped drive significant improvements in both diagnosis and treatment, particularly in the field of genetic testing. This progress has also spurred the creation of LDTs for new and more complex clinical purposes. According to one estimate, by 2016 more than 70,000 genetic testing products had come to market.¹

The following case studies illustrate some of the risks related to IVDs and highlight ways that stronger FDA oversight of the diagnostics market—both commercial IVDs and LDTs—can help mitigate these risks and protect public health.

Definitions

Analytical validity refers to how well a test detects or measures the presence of a given chemical compound, hormone, or genetic marker in a given sample. Analytically valid tests are precise (they provide a high degree of specificity), accurate (they measure or detect what they are intended to), and reliable (they regularly reproduce the same results).

Clinical validity refers to how accurately a test predicts the presence of, or risk for, a given condition. A genetic test intending to detect the presence of a genetic mutation is clinically valid for a particular cancer if a meaningful association between that mutation and the incidence of the disease has been sufficiently demonstrated.

Diagnostic testing for COVID-19

Widespread access to accurate, reliable testing is the cornerstone of the public health response to highly infectious pathogens such as SARS-CoV-2, the virus that causes COVID-19. Diagnostic tests are particularly important for confirming an active infection in an individual. Most COVID-19 diagnostic tests detect the presence of the virus's genetic material—specifically its RNA—or proteins on the virus's surface.² Those who test positive can either be referred for treatment or isolated to protect others and mitigate spread of the virus. More than 200 commercial IVDs on the market are intended to diagnose active COVID-19 infection, and many clinical labs have developed their own LDTs for in-house use.

The sensitivity and specificity of COVID-19 tests—that is, how reliably and accurately they identify an infected individual—varies. Antigen tests, which identify specific proteins on the surface of the virus, are generally less sensitive and more prone to false negatives than molecular tests, which detect the presence of viral RNA. However, antigen tests are typically faster and significantly easier and less expensive to run, and therefore can be distributed for use in a wider array of settings.³ Both types of tests have a role to play in addressing the spread of the coronavirus. In either case, it is important that a test intended for use in diagnosing an active infection meets baseline standards for quality and that the benefits of making the test available outweigh the risks.

When Secretary of Health and Human Services Alex Azar declared a public health emergency in February, FDA announced that all COVID-19 tests would first need to obtain an emergency use authorization (EUA), a step that would allow the agency to evaluate whether these tests met the appropriate standards. Because demand for testing soon outstripped supply, FDA subsequently issued a policy allowing laboratories to bring a COVID-19 test to market immediately, provided that labs submitted an EUA application within 15 business days. This flexibility allowed many tests to come to market more quickly.

Although the EUA process sets a lower bar for market entry compared with FDA's typical clearance or approval requirements for diagnostics, it provides some assurance that a test's benefits outweighed its risks. For example, when FDA evaluated a sample of 125 EUA requests for COVID-19 tests that had been submitted by laboratories, it found that almost two-thirds of them had design or validation problems that needed to be addressed before an EUA could be issued. FDA denied authorization entirely to several tests.⁴ The agency identified similar issues in the applications submitted by device companies.

These findings demonstrate that FDA review of diagnostics—especially during a public health emergency—is an important check on the quality of tests used on patients. Risk-based review of all tests also allows the agency to track which tests are on the market and obtain information on how they are performing in the real world. This ability, however, has been undermined by recent changes in policy by the Department of Health and Human Services, which only underscore the need for legislative reform (see box below).

Administration’s ruling makes legislative solutions imperative

In August 2020, the Department of Health and Human Services (HHS) announced that FDA does not have authority to require premarket review of LDTs, including tests for COVID-19, unless the agency goes through a lengthy rule-making process.⁵ This announcement means that makers of any new LDT—for diagnosing COVID-19 or for other purposes such as cholesterol, diabetes, and cancer screening—do not need any FDA review to demonstrate the accuracy of their products. Until the HHS announcement, FDA had maintained that all IVDs are subject to its regulation. However, it rarely enforced these requirements for LDTs before the start of the pandemic.

The HHS decision ended FDA’s ability to conduct even expedited reviews of LDTs, increasing the chances that an unreliable COVID-19 test could enter the market. It also casts doubt on FDA’s ability to protect patients if the agency learns of a faulty LDT that is already on the market. The initial statement did not specify whether FDA’s other regulatory authorities for diagnostics were still in effect. HHS later specified that FDA could still regulate tests under the Public Health Service Act, but because most of the agency’s authority over diagnostic tests—such as the power to conduct lab inspections or recall tests—stems from the Food, Drug, and Cosmetic Act, the agency’s power to regulate LDTs remains unclear.

Noninvasive prenatal testing

Noninvasive prenatal testing (NIPT) is a method of determining the risk that a fetus will be born with certain chromosomal or other genetic abnormalities, based on the analysis of a simple blood draw from a pregnant woman. All of the more than 40 noninvasive prenatal tests on the market are LDTs.⁶ None have been cleared or approved by FDA.

Importantly, NIPT cannot definitively determine whether an abnormality exists. Women with results indicating a higher risk of chromosomal problems should be offered a confirmatory diagnostic test—amniocentesis or chorionic villus sampling (CVS)—before making further decisions about the pregnancy.

When used appropriately—that is, in screening for disorders such as Down, Edwards, and Patau syndromes after the first trimester in certain high-risk populations—NIPT is an accurate and reliable tool that is less costly and less invasive than amniocentesis or CVS, both of which carry a small risk of miscarriage.⁷ However, the evidence to support the use of NIPT for women at lower risk is more limited than for those at higher risk, such as women age 35 and older.⁸ Furthermore, the rate of false positives may be high: A recent meta-analysis in the *British Medical Journal* noted that when NIPT is used in the general population, false positives for Down syndrome occur as often as 20% of the time and happen even more frequently for Edwards and Patau syndromes.⁹

Even when NIPTs are analytically and clinically valid and used in a clinically appropriate population, it is not always clear that patients or providers accurately interpret the results. Patients may not comprehend that NIPT is a screening tool, not a diagnostic test, and may make decisions about whether to continue a pregnancy based on incomplete information.¹⁰ False negatives from NIPT have also been reported, leading to parents who are unprepared for a child with a chromosomal abnormality, as well as delays in treatment and appropriate care for the baby.¹¹

Despite the limitations of NIPT, some companies advertise these tests for a broader range of uses than is currently recommended by professional medical societies, including screening for chromosomal disorders associated with missing or duplicated portions of a chromosome.¹² Companies may also encourage providers to offer NIPT in the first trimester of pregnancy. The evidence supporting these uses is limited.¹³

Although NIPT has enhanced the standard of care for many women and the accuracy of the test and its risk profile have improved over time, additional measures can help ensure the safe and appropriate use of these tests. FDA review and approval of NIPT would require developers to further define its target population and intended use, as well as adequately demonstrate the analytical and clinical validity of the test. This would help reduce the number of false positives and negatives, and lead to fewer negative consequences.

Test manufacturers would also be subject to FDA oversight regarding their product labels, much like with any other device regulated by the agency. This would help ensure the accuracy of the claims being made, which would in turn help physicians understand when and how to prescribe the tests and help patients interpret the results, including the need for follow-up testing after an abnormal result. Moreover, active FDA regulation of NIPT would help guarantee that the agency is receiving important information regarding adverse events and is able to monitor the quality of these tests.

Direct-to-consumer genetic testing

Direct-to-consumer (DTC) genetic tests—which individuals can order and use without involving a medical professional—have become increasingly popular.¹⁴ Consumers submit a DNA sample (often saliva or a cheek swab) and receive their results from the test developer via a secure website or written report, and in some cases get guidance from a certified genetic counselor.¹⁵ Many companies offer several different types of DTC genetic tests, such as ancestry tests, general wellness tests, screening for certain disease-causing genes, pharmacogenetic tests (to predict one's response to a medication), and genetic health risk tests (to predict a person's risk for developing diseases such as Alzheimer's, Parkinson's, and breast cancer by screening gene variants).¹⁶ Most companies offer these products as LDTs; only one company—23andMe—has received FDA clearance to market some of its tests,¹⁷ which it sought after FDA ordered the company to withdraw it from the market in 2013 for making unsubstantiated medical claims.¹⁸ According to one study, more than 26 million people had taken a DTC genetic health or ancestry test as of January 2019. That number could increase to 100 million in 2021.¹⁹

There are several concerns related to these tests. Though some companies have data demonstrating the analytical validity of their products, others may not. Consequently, there is variable quality among manufacturers.²⁰ One small study examined 49 patients who had taken a DTC genetic test and subsequently received follow-up testing. The authors found that 40% of the harmful variants reported back to those patients were false positives, indicating that the patients did not actually have those genetic variants.²¹ These incorrect results may lead to stress and unnecessary medical procedures that come with their own risks.

The National Institutes of Health recommends that before choosing a DTC genetic testing company, a consumer should ask if data exists to support the test and if the lab performing the test is certified or accredited.²² However, consumers may find it difficult to determine which tests they should trust or may not invest the time to fully understand the implications.

The clinical validity of some DTC genetic tests is also uncertain, particularly for genetic health risk tests. Scientists disagree about the role that different genetic variants play in contributing to disease. In many cases, several genes or gene variants may play a role, making it difficult to accurately calculate risk. Moreover, it is not

clear whether such information is medically helpful to the prevention, management, or treatment of disease, especially in cases where no effective interventions exist. Even when they do, the value of DTC testing has been questioned: A 2017 study found that many adults who received elevated cancer risk estimates from DTC genetic testing did not significantly change their diet, exercise, advanced care planning, or cancer screening behavior in an effort to detect or prevent disease.²³

Finally, in many instances, a health care provider may not be involved in any part of the DTC genetic testing process, from acquisition to interpretation of results, which raises the stakes for ensuring consumer information is accurate, balanced, and lay-friendly.²⁴ Consumers may not understand that the tests are not predictive of disease or may not know how to interpret the meaning of increased or decreased risk without the guidance of a professional. This may lead to undue anxiety, or conversely to false reassurances following an incorrect result or interpretation. In either case, consumers could make misguided medical decisions.²⁵

FDA review and oversight of DTC genetic tests including LDTs would alleviate some of these risks by requiring evidence to demonstrate that these tests are analytically and clinically valid and appropriately labeled. Such labeling would communicate information about a product's risks and benefits and an interpretation of results, and could clearly direct patients to seek confirmatory testing and genetic counseling with a trained provider before making health care decisions based on the result of a DTC test. FDA regulation also helps ensure the continued quality and accuracy of a test once on the market.

Companion diagnostics

A companion diagnostic is an IVD intended to guide the safe, effective use of a particular therapy.²⁶ For example, a companion diagnostic can identify patients who are most likely to respond well to a particular drug or those likely to experience serious side effects. These tests can also be used to monitor a patient's response to a drug to facilitate adjustments in treatment.²⁷ When used appropriately, companion diagnostics can improve a patient's likelihood of survival and quality of life by directing a physician to prescribe the optimal treatment.

FDA has approved more than 30 companion diagnostics, including IVDs that test for particular mutations in skin, colorectal, lung, and other cancer tumors.²⁸ However, once these companion diagnostics are approved by FDA, LDT developers often create "follow-on" co-diagnostic tests that they claim will identify the same mutations.²⁹ In some cases, this does not pose risks to patients. For example, a 2018 study comparing LDTs and FDA-approved tests for three specific genetic mutations found that they had comparable performance.³⁰ However, the results of this study cannot necessarily be extrapolated to other kinds of co-diagnostic tests, which vary substantially in terms of their complexity.³¹ Because individual labs may have different approaches to analyzing samples—particularly for newer, more complex tests—the same patient may get different results depending on the LDT used.³² Though some variability in test results is normal, FDA review would set baseline requirements for test performance and validity, which would ensure greater consistency across testing sites and reduce the likelihood of incorrect results being reported back to patients.

Some LDT developers also claim to test for additional mutations that have not been adequately reviewed to predict drug response.³³ The use of unapproved companion diagnostics can present significant risk to patients, who may receive ineffective therapies for a condition or miss out on more beneficial ones. And many cancer treatments have serious side effects of their own, which can compound the harm for patients who receive an inappropriate therapy.³⁴

Although testing is generally just one part of any treatment decision-making process, companion diagnostics in particular can be a key factor in a treatment decision, increasing the risks to the patient if the results are incorrect. FDA oversight of these higher-risk tests would require developers to demonstrate that the test is analytically and clinically valid for its intended use and would allow FDA to evaluate the manufacturer's claims for accuracy. This would reduce the risks associated with companion diagnostic tests and help ensure that patients receive appropriate drug treatments. FDA review would also level the playing field, ensuring that all test developers are held to the same evidentiary standard.

Conclusion

These case studies highlight some of the risks associated with diagnostic tests. Patients and providers should be able to trust their test results for any condition, regardless of where the test is performed, especially when making critical medical decisions. FDA review and oversight would help guarantee this by setting a baseline for the analytical and clinical validity of all tests on the market and by ensuring that the claims made for these tests are truthful, nonmisleading, and based on sound evidence.

The bipartisan VALID Act would make clear that LDTs are subject to FDA's review requirements for IVDs. It would also provide the agency with the tools necessary to monitor the diagnostic market and protect patients when safety concerns arise with a test. Congress should move quickly to consider such proposals and approve legislation that establishes a unified, risk-based FDA regulatory system for diagnostics, including LDTs.

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