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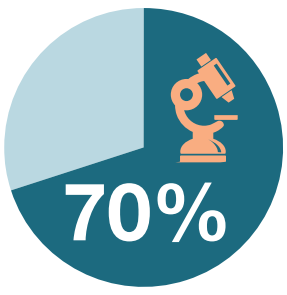
Diagnostic Tests are Critical to Health Care

The Essential Role of FDA

Diagnostic tests are tests performed on samples taken from the body, and used in a broad range of applications to diagnose health conditions and guide treatment options. These tests are also referred to as **"in vitro diagnostics"** or "IVDs."

Diagnostic tests are often the **least expensive** component of the health care pathway, yet they **influence** more than 70 percent of health care decisions.



There are **tens of thousands** of different diagnostic tests available today.

Diagnostic tests are performed close to **7B** times each year in the United States.

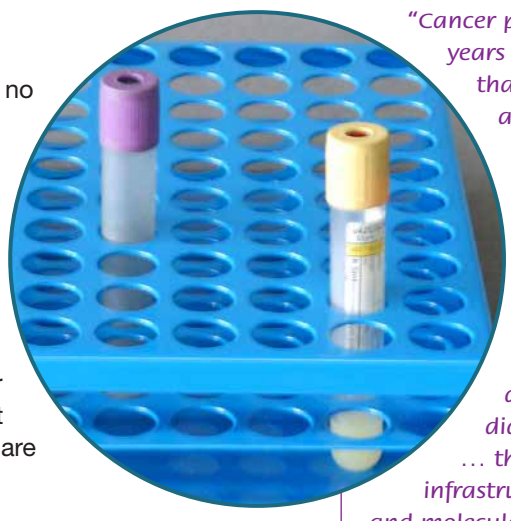
What is the Problem?

Lack of Food and Drug Administration oversight means no independent assurance of safety and effectiveness.

Historically, FDA did not exercise its oversight authority over LDTs because they were typically low risk tests with well-established test methods or used in low volume.

Now, however, LDTs have become more complex and even the most advanced molecular diagnostics — such as genetic tests that guide choices among cancer treatments or tests used in the diagnosis and treatment of common and serious or life threatening disorders — are regularly developed by laboratories.

Leading patient groups have expressed concerns that lab developed tests do not undergo the scrutiny of other diagnostic tests leading to serious concerns about their validity and the patient impact.



"Cancer patients have in recent years suffered harm from LDTs that did not provide the accurate and meaningful information that was promised…"

—Cancer Leadership Council

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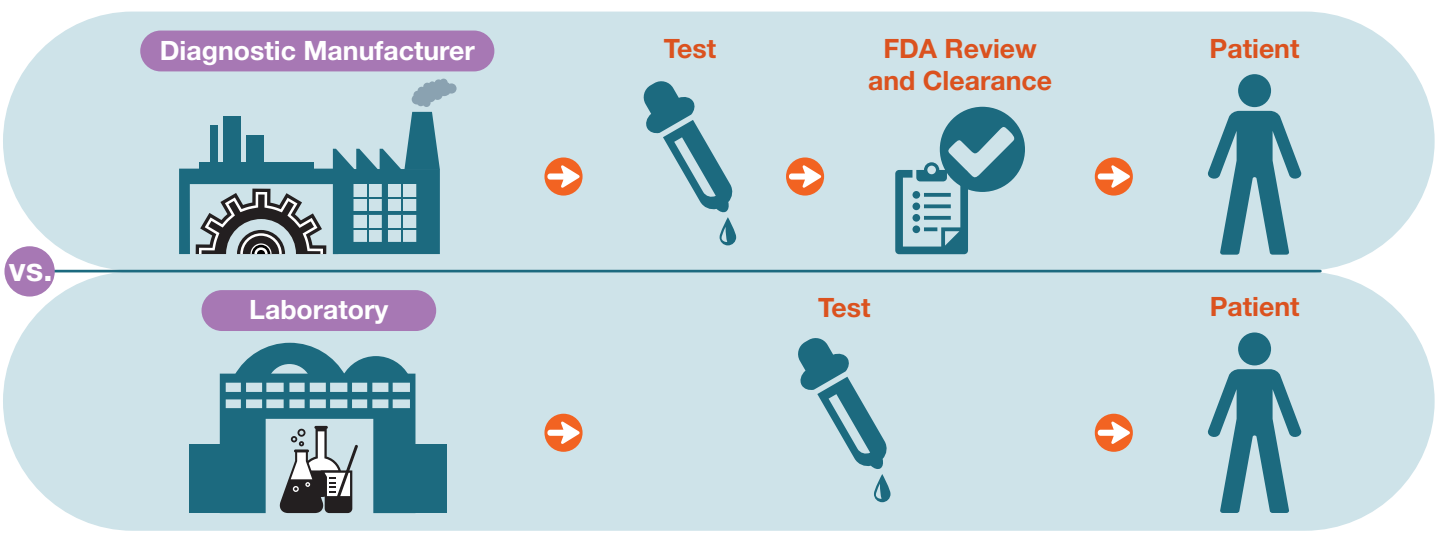
"Patients and their physicians need to be able to be confident that diagnostic tests are accurate … the current regulatory infrastructure for genetic tests and molecular diagnostics have important gaps…"

—United Healthcare

What are Laboratory Developed Tests?

Diagnostic tests are developed either by manufacturers for distribution to laboratories or by laboratories themselves for use in their facilities. The tests developed by labs are referred to as laboratory developed tests (LDTs).



CMS* Laboratory Regulation is *Not* a Substitute for FDA

Unlike FDA oversight of diagnostics, CMS:

- ✖ Does **not** regulate the safety and effectiveness of diagnostic tests;
- ✖ Does **not** require pre-market review of tests;
- ✖ Does **not** require demonstration of clinical validity;
- ✖ Does **not** require systematic adverse event reporting;
- ✖ Does **not** have a process for corrections or recalls.

What is the Solution?

FDA has announced a plan to apply existing diagnostics regulations to LDTs under a risk-based approach.

- High and moderate risk tests will be subject to FDA pre-market review to assure safety and effectiveness.
- All clinical laboratories that perform LDTs will be required to report adverse events to FDA.
- Several categories of LDTs will be exempt from pre-market review, including low risk tests, rare disease testing, traditional LDTs, and unmet needs LDTs
- FDA will implement a risk based phased in approach to support test continuity

"Unfortunately, FDA is also aware of faulty or unproven LDTs, including problems with several high-risk LDTs such as: claims for diagnosing ovarian cancer that are not adequately supported with evidence; lack of appropriate controls yielding erroneous results; and falsification of data for determining which breast cancer therapy would be most beneficial."

—FDA Testimony to House Energy & Commerce Health Subcommittee, September 2014

"The increasing reliance on diagnostic tests in clinical decision making, combined with the dramatic shift in the number and complexity of LDTs being offered, are posing increasing risks to patients. FDA has been made aware of a number of examples where clinical decisions made on the basis of faulty tests resulted in harm to patients. As a result, FDA has been developing a risk-based framework for regulatory oversight of LDTs that would assure that tests, regardless of the manufacturer, have the proper levels of control to provide a reasonable assurance of safety and effectiveness, while also fostering innovation and progress in personalized medicine."

—FDA Report: *Paving the Way for Personalized Medicine*, FDA, October 2013

*Centers for Medicare and Medicaid Services

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