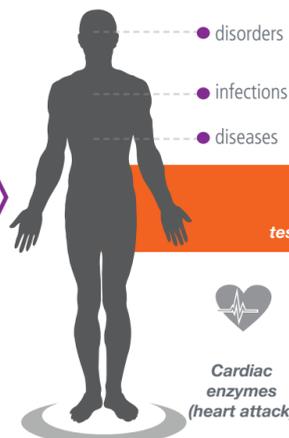


# MEDICAL DIAGNOSTICS

In vitro diagnostics (IVDs) are performed on samples taken from the body, such as blood or tissue.



THESE TESTS HELP IDENTIFY:



DIAGNOSTICS PROVIDE CRITICAL INSIGHTS AT EVERY STAGE OF CARE



**4,000**  
tests available for clinical use

**6.8B IVD**  
tests performed each year

## THE VALUE OF DIAGNOSTICS

Diagnostic tests are at the forefront of medical innovation, providing vital insights into patient health and care.

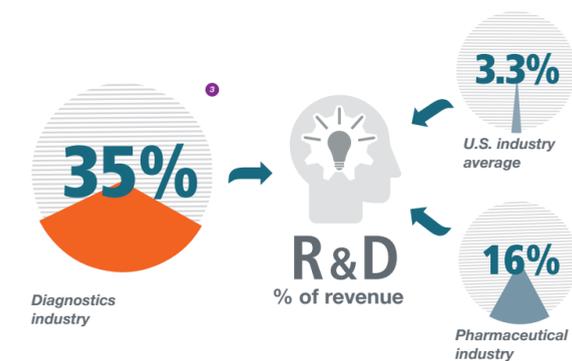
PERCENT OF WORLDWIDE HEALTH CARE SPENDING USED ON DIAGNOSTICS



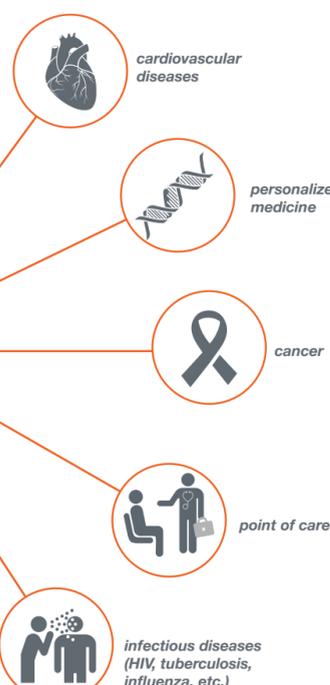
PERCENT OF MEDICAL DECISION-MAKING INFLUENCED BY DIAGNOSTICS



Diagnosics represent only 2% of overall health care spending, but are critical to medical decision-making, leading to better patient outcomes, lives saved and often reduced health care costs. There is huge potential for relatively low cost tests to greatly reduce the burden of diseases that cost billions of dollars every year.



Diagnosics Research and development spending is 10 times the average among U.S. industries.



TAMIKA FELDER

My cancer experience started in 2001, I was 25 years old and diagnosed with advanced cervical cancer. For me it wasn't so much having the cancer, but the journey to getting the diagnosis. I'm so very grateful that one, there was a diagnostic test that detected my cervical cancer and two, that I had great doctor and great team and they could read that test and knew immediately what to do to save my life. Today, I'm cancer free, and I'm healthy and happy and I want to make sure that if I'm diagnosed with anything it's in the early stages, so I can treat it and knock it out.

### DIAGNOSTICS CAN LOWER HEALTH CARE COSTS



DIAGNOSTICS CAN DECREASE HEALTHCARE-ASSOCIATED STAPH INFECTION RATES BY 70%. IF NOT PREVENTED, STAPH INFECTION TREATMENT CAN COST AS MUCH AS \$19,000

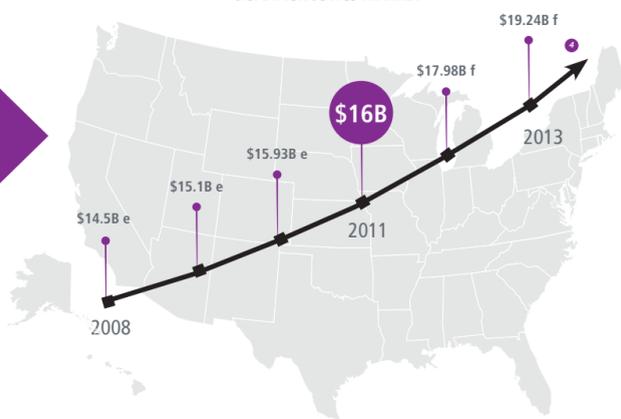
## DIAGNOSTICS: A VITAL AMERICAN INDUSTRY

GLOBAL DIAGNOSTICS MARKET



40%

U.S. DIAGNOSTICS MARKET



U.S. DIAGNOSTICS JOB MARKET

40,500 jobs

\$63K /yr. salaries



180 companies

## REFORM IS NEEDED TO IMPROVE PATIENT CARE

### MODERNIZE THE DIAGNOSTICS PAYMENT SYSTEM

- The current Medicare framework for payment of diagnostic tests is flawed and outdated. It fails to reflect the real value of modern diagnostic tests, dampens incentives for innovation, and slows access to new tests.
- Private health insurers largely base their payment models for tests on the Medicare schedule.
- More than a decade ago, the Institute of Medicine reported that the outdated Medicare payment system could threaten patients' access to care and the use of enhanced testing methodologies in the future. [Institute of Medicine, 2000]
- Patients deserve a system that encourages the development of innovative and life-changing diagnostic technologies.

### ENSURE EFFECTIVE, RISK BASED REGULATION

- All diagnostics should be overseen by the Food and Drug Administration (FDA) under a risk-based approach that ensures timely patient access to safe and effective diagnostic tests.
- Focus FDA resources on tests that pose the highest risk to patients - regardless of whether made by manufacturers or clinical laboratories (FDA is currently not exercising its oversight authority over laboratory developed tests, or LDTs).
- Expedite patient access to lower risk tests by more efficient use of the pre-market review process, including exemptions for well-established tests.
- FDA has regulatory authority over all diagnostic tests. To support public health and assure the safety and effectiveness of diagnostics, FDA has announced plans to implement its enforcement authority over LDTs through implementation of a risk-based regulatory framework.



"Thirty years ago, 50-55% would experience a recurrence and eventually die from breast cancer and today, the numbers are below 20%. This is the best example of how we've made progress because of early diagnosis and personalized treatments that require exact diagnostic testing."

Stefan Glück, M.D., Ph.D  
Professor in the Department of Medicine  
University of Miami

SOURCES:

- Lewin, Laboratory Medicine: A National Status Report, p. 3
- Lewin, The Value of Diagnostics Innovation, Adoption and Diffusion; July 2005
- RNCOS, Global In Vitro Diagnostic Market Analysis; p. 112, Dec 2011
- RNCOS, Global In Vitro Diagnostic Market Analysis; p. 60-4, Dec 2011
- Lewin, The Value of Diagnostics Innovation, Adoption and Diffusion; July 2005

AdvaMedDx member companies produce advanced, in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as a division of AdvaMed, the medical device trade association, AdvaMedDx is the only advocacy organization exclusively addressing policy issues facing diagnostic manufacturers both domestically in the United States and abroad.

For more information, visit [AdvaMedDx.org](http://AdvaMedDx.org)



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