Diagnostics, which are used to pinpoint a patient’s disease or condition, encompass laboratory tests, imaging techniques and screening. By facilitating early and proper diagnosis, these tools work to ensure patients receive the right care at the right time, saving lives and dollars.

Today:
- Seven billion laboratory tests are conducted annually in the U.S.*
- More than 4,000 different diagnostics are currently available for clinical use.†
- Over 30% of adults ages 50 to 75 did not receive their annual recommended colonoscopy to screen for colorectal cancer in 2013. Furthermore, that same year, 20% and 28% of women did not receive their recommended mammogram (to screen for breast cancer) or Pap test (to screen for cervical cancers) respectively.‡
- An estimated 40% of all primary care visits include a laboratory diagnostic test.§
- Between 6 and 17% of adverse events occurring in hospitals are due to diagnostic errors, including 10% of patient deaths, underscoring the need for new and improved diagnostic technologies. ¶

HOW RESEARCH SAVES LIVES:
- Severe Combined Immunodeficiency Disorder (SCID) is a treatable disease if diagnosed and treated early; otherwise it causes death before a child’s first birthday.*
- More than 90% of women diagnosed with stage I and II breast cancer survive for 5 years following their diagnosis, compared to just 22% of women diagnosed with stage IV breast cancer. Since 1990, breast cancer mortality in the U.S. has fallen by one third, in part due to early detection through the use of mammograms.¶
- Gene sequencing diagnostics performed by NIH-funded researchers at Children’s Mercy Hospital in Kansas City observed that in children affected by brain abnormalities or unknown disorders, genome screening helped 45% receive diagnoses and 49% receive a new treatment for their disorder.¶

HOW RESEARCH SAVES MONEY:
- Early detection of methicillin-resistant staphylococcus aureus (MRSA) using a new rapid polymerase chain reaction (PCR) diagnostic test allowed physicians to prescribe appropriate antibiotics nearly two days sooner, reducing the length of hospital stays by 6.2 days and lowering hospital costs by more than $21,000 per patient.‡
- Newborn screening for congenital hypothyroidism (CH), which causes intellectual disability if not diagnosed and treated early, results in an annual savings of $400 million, or 20 times the cost of the diagnostic tests utilized.¶
- It is significantly less expensive to screen for and treat early-stage lung cancer compared to late-stage lung cancer. The mean cost per person for diagnostic workup, curative intent surgical treatment, and 2 years of follow-up is 30% less than the cost of treating advanced-stage lung cancer with chemotherapy, radiotherapy, and supportive care.¶

The Cost:
- An estimated 20% of colon cancer fatalities in low-income communities could have been avoided with early detection. Beyond the devastating human cost, these preventable deaths are associated with an economic burden of $6.4 billion annually.*
- Laboratory diagnostics are estimated to influence up to 70% of clinical decision-making, but account for just 2% of total health care costs.¶

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† CENTER FOR DISEASE CONTROL AND PREVENTION <WWW.CDC.GOV>
‡ ADVANCED DX <ADVAMEDI.COM>

perspective:

Vince Forlenza, Chairman, CEO and President, BD

“Diagnostic tests inform the large majority of the health care decisions made each and every day. From blood tests to detect infectious disease to genetic tests that identify cancer variants and match patients to the most appropriate treatment, diagnostics play a critical role in health care delivery and often reduce overall health care costs. Early and accurate diagnosis is the best way to keep patients out of the hospital and prevent disease escalation.”

+ SODEN SE ET AL. SCIENCE TRANSLATIONAL MEDICINE 03 DEC 2014
* NATIONAL CANCER INSTITUTE <WWW.CANCER.GOV>
AMERICAN CANCER SOCIETY <WWW.CANCER.ORG>
‡ CRESSMAN ET AL. J THORAC ONCOL. 2014 OCT; 9(10): 1449–1458.
+ CENTER FOR DISEASE CONTROL AND PREVENTION <WWW.CDC.GOV>
* AMERICAN COLLEGE OF RADIOLOGY <WWW.ACR.ORG>
Hope for the Future:

:: While PCR diagnostic tests are becoming increasingly common, the need for infrastructure and electricity has limited the use of these tests in rural and remote areas. NIH-funded researchers at Cornell University are developing a nucleic acid based diagnostic PCR that can be run by a smartphone and utilizes solar power. *

:: Current diagnostic tools only allow clinicians to identify the cause of 20% of pneumonia cases acquired outside healthcare settings. Next generation diagnostics are expected to identify the cause of as many as 75% of pneumonia cases. This improvement would greatly reduce unnecessary antibiotic use, in turn reducing the emergence of antibiotic-resistant infections, improve quality of care and work to minimize wasteful healthcare spending. *

* JIANG ET AL. SCIENTIFIC REPORTS 2014 FEB 20; 4:4137.
^ INFECTIOUS DISEASE SOCIETY OF AMERICA <WWW.IDSOCIETY.ORG>

uses of diagnostics:

SCREENING, EARLY DISEASE DETECTION: To identify asymptomatic or pre-symptomatic individuals or those at an increased risk for a specific condition or disease. This information allows for prevention and/or early intervention, which is associated with greatly improved prognosis for many patients.

Example: Blood cholesterol tests for heart disease

DIAGNOSIS: To aid in the clinical diagnosis of a condition once symptoms or other evidence suggests, but does not definitely prove the presence of a disease.

Example: X-ray to visualize a broken bone

DISEASE STAGING, PROGNOSIS: To measure the severity or progression of a diagnosed disease, the mortality risk, likelihood of remission or probability of adverse health outcomes. This information can be very valuable to clinicians when making treatment decisions.

Example: CD4 count to monitor HIV progression

DRUG SELECTION, TREATMENT MONITORING: To provide information to help doctors target or personalize a treatment to an individual.

Example: Measuring international normalized ratio (INR) in patients taking warfarin for blood clots

DISEASE OR CONDITION MONITORING AND MANAGEMENT: To provide clinicians with information about the progression, success, adverse effects, or outcomes of a given treatment. This information guides future decision making for further treatments or testing.

Example: Blood glucose tests and HbA1c tests for diabetes

SOURCE: ADVAMED, NATIONAL LIBRARY OF MEDICINE, MAYO CLINIC

The Bottom Line:

The pivotal importance of diagnostics is clear; these tools empower the delivery of timely, effective and efficient health care. Public and private sector investment in diagnostics, coupled with policies that ensure timely access to them, holds tremendous promise for saving lives and dollars.