

The Value of Clinical Laboratories

Supporting Patient Health & Medical Innovation

Key Highlights

- America's clinical laboratories serve as the foundation for early diagnosis, prevention and personalized care for millions of patients.
- From routine blood tests to ground-breaking genetic and molecular diagnostics, clinical laboratories play a vital role in improving patient outcomes and quality of life while delivering better value for the health system on the whole.
- Clinical laboratories serve as a driving force in medical innovation. The growing demand for laboratory developed tests (LDTs) – clinical diagnostics that are often designed in response to unmet clinical needs – has revolutionized our approach to patient care and provides an essential foundation for future medical breakthroughs and “moonshots.”

Supporting the Next Generation of Precision Medicare and Care Delivery

Our advancement in precision medicine represents a new frontier in care delivery. Today, newly-developed LDTs, including innovative genetic tests, are changing the face of patient care. The ability to customize treatment plans tailored to an individual patient's genetics or other biomarkers is a direct byproduct of clinical diagnostic innovation. Diagnostic tools are also an essential part of daily monitoring and management of chronic disease, including diabetes, heart disease and cancer.

For example, in the fight against cancer, LDTs have supported new immunotherapy treatments that boost a patient's own immunity and defenses to fight the disease – without the harsh effects of chemotherapy or radiation. For rare diseases and conditions that still need a treatment or cure, clinical laboratory diagnostics help bring focus to the specific condition, its symptoms and side effects while providing essential data on treatment and disease response to inform the next generation of cures.

Less invasive testing, like *in vitro* testing and liquid biopsies, have fundamentally changed the way we identify, approach and treat some of the most challenging conditions facing patients, such as infectious diseases and tissue-based cancers.

Finally, our advances in genomic testing demonstrate the power of clinical diagnostics to drive medical progress and transform the ways in which we treat and target disease. Genomic testing only a few years ago was limited to patients with certain solid tumors (e.g. melanoma, lung cancer and colon cancer). Today, targeted tumor-sequencing tests can be used for any tumor – regardless of where in the body the cancer started. This technology has the ability to screen hundreds of genes for cancer tumors in an unprecedented way, allowing providers to assess whether a tumor is susceptible or responsive to certain drugs. As a result, genomic testing guides better treatment or prevention options for patients when they first need it, avoiding trial and error to identify the best course of action.

Addressing System-Wide Cost and Disparity Challenges Through Prevention, Early Diagnosis

Prevention and early detection are not only beneficial to patient outcomes and quality of life, they also drive savings across the health system by helping to identify diseases and risk factors for diseases at an early stage. Diabetes alone, for example, is associated with \$16 billion in annual spending that could have been avoided through earlier diagnosis and better disease management¹. For many diseases, a test that may cost \$20-30 can ultimately save the system thousands of dollars by deterring costly complications and procedures in the future.

Routine screenings and cutting-edge diagnostics can help identify risk factors and early signs of disease before it progresses, giving patients and providers the opportunity to prevent or address the condition before it starts or at an earlier stage. For instance, a routine cholesterol screening might reveal risk for heart disease. If a patient is able to take preventive measures and make lifestyle changes, they can reduce their risk for adverse health outcomes and the costly complications associated with treating and managing cardiovascular disease.

¹ HealthITAnalytics. (2016, April 01). Preventable Diabetes Care Costs Total \$16 Billion Per Year. Retrieved March 19, 2019, from <https://healthitanalytics.com/news/preventable-diabetes-care-costs-total-16-billion-per-year>