



Laboratory Medicine:
*Advancing Quality in
Patient Care*

ADLM

Association for
Diagnostics &
Laboratory Medicine





Introduction to Laboratory Medicine

Laboratory medicine is integrated into the daily practice of virtually every clinician. Whether measuring cholesterol levels to determine a patient's risk for cardiovascular disease or sequencing the DNA of tumors to help decide the best choice of chemotherapy, clinical laboratories provide the test results needed throughout a patient's life for clinicians to assess health, diagnose disease, and to plan and monitor treatment. Additionally, clinical laboratories help protect the blood supply and transplant recipients from harmful pathogens, and they help determine illegal drug use, drug abuse, and drug overdose. Clinical laboratorians

Clinical laboratory professionals generate new and innovative tests that help advance precision medicine and healthcare in general.

generate new and innovative tests that help advance precision medicine and healthcare in general, and they work with clinicians to integrate informatics and other laboratory data into clinical practice guidelines and evidence-based medicine.

In the U.S., approximately 13 billion laboratory tests are performed annually in more than 200,000 Clinical Laboratory Improvement Amendment (CLIA)-certified laboratories. Laboratory services comprise only 2.3 percent of U.S. healthcare expenditures and two percent of Medicare expenditures, yet laboratory medicine is integral to the healthcare system

and the patients it serves. Laboratory tests are included in nearly 25% of U.S. patient care quality indicators for adults.

Laboratory medicine professionals play a critical role in ensuring high-quality, cost-effective clinical care by informing clinical decision makers with objective scientific data and informed interpretations of results.



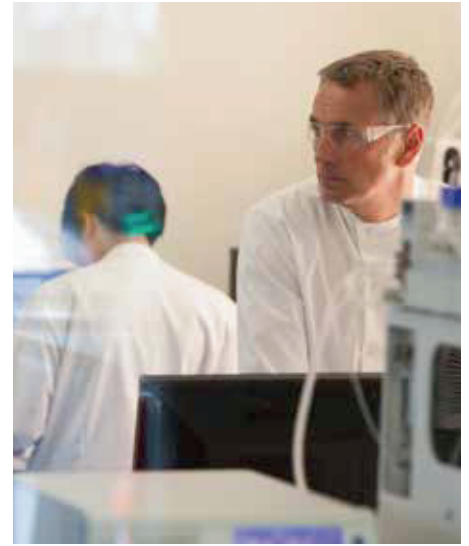
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Introduction to Laboratory Medicine	i
About Laboratory Professionals	2
Lab Tests Across the Lifespan.....	3
Case Studies on Advances in Laboratory Medicine.....	4
Cardiovascular Disease	5
Diabetes	7
Cancer	9
Infectious Diseases	11
Laboratory Medicine: The Future of Healthcare	13



About Laboratory Professionals

Clinical laboratories are overseen by laboratory directors and staffed by individuals with varying levels of expertise and wide-ranging areas of scientific focus. To ensure the best possible performance, all laboratory personnel are required to engage in continuing education and maintain technical certification.



Patient encounters typically occur with phlebotomists, who draw blood for testing and have a combination of formal and on-the-job training. Other laboratory personnel include clinical laboratory scientists (also referred to as medical technologists)—professionals who have four-year degrees in a relevant scientific discipline—and clinical (or medical) laboratory technicians, professionals with two years of targeted scientific education. The professional roles of these individuals can range from bench technician (a person who runs the tests on specialized equipment) to laboratory manager or supervisor, who oversees laboratory operations, conducting quality control and other activities to maintain regulatory compliance.

Laboratory directors hold advanced degrees in science or medicine and bring a unique expertise to the healthcare team.

Laboratory directors (also known as medical directors of the laboratory) are highly educated individuals who typically hold doctoral degrees (**MD, PhD, or MD/PhD**). Laboratory directors work in multiple settings, including hospital laboratories, academic settings, and reference laboratories through community doctors order tests. Most MD or MD/PhD lab directors are pathologists by medical training, while PhD lab directors have Board-certified for-

mal training in clinical chemistry, immunology, medical/molecular genetics, microbiology, or the newer specialty of pharmacogenetics. Lab directors oversee all scientific and business aspects of the laboratory, including ensuring the laboratory meets all quality standards and regulatory requirements. They also interface with clinical colleagues on issues of test utilization and interpretation and determine the optimum instrumentation and equipment to efficiently meet clinical needs and effectively reduce the cost of care. In the age of personalized or precision medicine, laboratory directors bring their deep scientific knowledge to developing and delivering companion diagnostics that guide clinicians in diagnosis and treatment decisions, such as drug and dose selection that is right for the patient. Given their critical scientific expertise and applied knowledge of the latest tests and methods, laboratory directors bring a unique and vital perspective to the healthcare team.

Together, laboratory professionals play a vital role in providing high quality patient care.

Lab Tests Across the Lifespan

Throughout an individual's lifespan, laboratory tests contribute to improved overall health and better disease management. In addition to testing performed to diagnose specific conditions and monitor treatment, lifelong health screenings are a cost-effective preventative measure that can detect risk early, leading to better prognoses and more favorable outcomes. Health complications and death associated with heart disease, stroke, and cancer, for example, have been significantly prevented through evidence-based screenings and preventative services.

Many individuals' first lab test occurs immediately after birth through newborn screening to diagnose inherited disorders or jaundice. Whether a baby has sickle cell disease or cystic fibrosis, a heel stick of blood can save lives by enabling the right treatment and therapies sooner. Neonatal screening has well proven clinical value and cost-effectiveness compared to the cost of caring for an individual who may require lifelong support.

Children aged two to 12 years might be screened for diabetes, obesity, high cholesterol, tuberculosis, iron deficiency anemia, and lead poisoning during annual "well" visits, depending on determined risk. Young children are especially vulnerable to the harmful effects of these health conditions. According to the CDC, about 250,000 children between one and five years old have blood lead concentrations above recommended levels. At the same time, the rate of obesity has more than doubled in children and quadrupled in adolescents in the past 30 years. While children generally

require few laboratory tests, early screening and intervention can help prevent serious and costly health problems in the future.

In teenagers (13 to 18 years old), additional screenings for sexually transmitted diseases are indicated, even while clinicians continue to follow screening guidelines on the same conditions as for younger children. With adolescent girls and young women having the highest rates of chlamydia and gonorrhea of all US demographic groups, the CDC recommends annual screening of at-risk groups for these diseases. The agency further recommends annual HIV screening for anyone with increased risk of infection and transmission, including youths aged 13 to 24, who account for 25% of the roughly 50,000 new HIV infections each year.

Screening recommendations for adults vary with age, life stage, and health status. Clinicians routinely perform blood tests to screen for diabetes and measure cholesterol levels. Additionally, adults of childbearing age may seek genetic testing to determine their risk of passing

Common or routine lab tests at different ages



Children (0-12)

- Newborn Screening
- Diabetes
- Obesity
- Cholesterol
- TB
- Anemia
- Lead Poisoning



Adolescents (12-18)

- Childhood Screening
- STD Testing



Adults (19-49)

- Diabetes
- Cholesterol
- Genetic Testing
- Hepatitis
- Cancer Screening



Adults 50+

- Adult Tests/ Screening
- Osteoporosis
- Thyroid Testing

inherited disorders or diseases to their children. After conception, women receive counseling and laboratory testing throughout the pregnancy from the first to third trimester to determine and monitor the patients' health.

In adults aged 30 to 49, physicians continue to check for all conditions assessed as young adults with the addition of hepatitis C, colorectal and prostate cancer. For example, routine cervical and colorectal cancer screenings have resulted in 14% fewer deaths.

Adults over the age of 50 continue to be monitored for various adult-onset conditions, plus osteoporosis and thyroid dysfunction. There is no age for screening discontinuation, except for prostate and cervical cancer in those older than 65 years.

Case Studies on Advances in Laboratory Medicine

Laboratory medicine professionals consistently address today's complex, changing healthcare environment to offer their vital professional expertise to clinicians to support better patient outcomes. Laboratorians have made a positive impact on patient health in many ways, improving the diagnosis and treatment of many diseases and conditions, including cardiovascular disease, diabetes, cancer, and infectious disease. Case studies on each of these impactful examples follow.

Cardiovascular Disease Facts

CVD include a wide range of disorders that impact the heart and blood vessels. The diseases falling into this category include not only "classical" conditions, such as myocardial infarction (MI, heart attack) and congestive heart failure, but chronic kidney disease.

- ▶ Cardiovascular diseases are one of the leading causes of death globally, with about 17.5 million people dying from related diseases, according to the World Health Organization in 2015.
 - About 7.4 million deaths are due to coronary heart disease.
 - About 6.7 million are stroke-related deaths.
- ▶ In the USA in 2011, cardiovascular disease was the #1 cause of death.
- ▶ Stroke is the third most deadly health issue amongst men and women.
- ▶ More than 1 in 3 (83 million) adults currently live with one or more types of cardiovascular disease.
- ▶ In 2010, total cost estimates of cardiovascular diseases in the USA were \$444 billion.
- ▶ Addressing risk factors like tobacco use, alcohol abuse, unhealthy diet, obesity, and lack of physical activity can prevent death due to cardiovascular disease.

Cardiovascular Disease

The Laboratory's Role

Clinical laboratory testing in Cardiovascular Disease (CVD) varies by the purpose and type of test—whether to determine risk, identify specific disease, or monitor treatment.

The laboratory has long played a critical role in identifying individuals at risk of CVD through measurements of various lipids during regular well visits. Elevations in total and LDL cholesterol and triglycerides, along with decreases

Advances in laboratory medicine, such as troponin and BNP testing, have significantly improved early identification of CVD.

in HDL cholesterol, are associated with a higher risk of heart attack and stroke. Early identification of risk enables lifestyle changes or drug therapies to reduce that risk.

For diagnosing acute coronary disease, clinical laboratory professionals have developed a sophisticated test that measures troponin, a heart tissue protein that is seen at increased levels in the blood after a heart attack. Elevated troponin may be the only indicator of heart attack in patients without chest pain or with very mild CVD symptoms (for example, most women and patients with diabetes) and is among the key diagnostic cri-

teria used in the emergency room. Even mildly increased amounts of troponin indicate heart damage or injury, signifying the need for further evaluation.

Many patients who have a heart attack develop congestive heart failure (CHF), a condition in which the pumping of the heart is weakened by damage and various ensuing factors. As the heart weakens, the kidneys cause the body to retain fluid and salt, and the build-up of fluid in the lungs causes shortness of breath. During this process, the body makes B-type natriuretic protein (BNP), which is not present in other causes of shortness of breath. BNP testing allows physicians to differentiate CHF from other causes of shortness of breath and to monitor treatment through ongoing testing.

Advances in laboratory medicine have produced tests that are very sensitive to changes in heart function or health, such as troponin and BNP, and have contributed to significant improvements in the early identification of patients at risk for CVD and in managing their overall care.

Diabetes Facts

Diabetes is a group of conditions defined by abnormally high blood glucose caused by the body's inability to adequately produce (type 1 diabetes) and/or respond to (type 2 diabetes) insulin. Other classifications of diabetes exist, such as gestational diabetes.

- ▶ 29 million people in the USA had diabetes in 2014, up from 26 million in 2010.
- ▶ At least 86 million Americans have prediabetes and almost 90% are unaware.
- ▶ Diabetes is the 7th leading cause of death in the USA.
- ▶ Diabetes can damage the kidneys, nerves, heart, eyes, and skin.
- ▶ Total annual cost of diabetes in the USA was \$245 billion in 2012 – an increase of 41% since 2007, according to the American Diabetes Association (ADA).
 - Direct medical costs equaled \$176 billion.
 - Reduced productivity cost \$69 billion.



Given the impact of diabetes on the individual and the public, the U.S. Preventive Services Task Force and the ADA recommend all adults over 45 years of age, all younger overweight adults with any additional risk factors, and overweight children with at least two additional risk factors be tested. When prediabetes is detected in asymptomatic patients, clinicians can recommend changes to patients' diet and lifestyle to delay the onset and complications of diabetes.

The diagnosis of diabetes begins with laboratory measurements of blood glucose and hemoglobin A1c (HbA1c), a test that evaluates the average amount of glucose in the blood over the previous two to three months. Because diabetes im-

By standardizing HbA1c testing, the laboratory community greatly enhanced the ability of clinicians to interpret and apply these results consistently in the care of patients with diabetes.

pacts virtually every organ of the body, additional tests, such as cholesterol and urine albumin, are performed to detect and monitor complications, including damage to the heart, blood vessels, and kidneys. These key tests are routinely repeated throughout the patient's life to determine the effectiveness of treatment. Additional testing is performed when the type or cause of diabetes is unclear (genetic and autoimmune markers) and when patients suffer complications.

Since the 1990s, the laboratory community has worked to standardize HbA1c to optimize its clinical effectiveness. Prior to the HbA1c standardization initiative led by laboratory medicine professionals, HbA1c results could vary over time and among laboratories because measured values would often differ between methods. Physicians had difficulty determining whether different HbA1c results were evidence of the patient's levels changing or if the results shifted because different methods were used. Standardization means patient results from different laboratories or methods will be uniform and comparable, so physicians can appropriately use them to improve patient care through more effective disease management.

The tests developed and performed by laboratory professionals greatly contribute to physicians' ability to diagnose diabetes earlier, to adjust drug therapies, and to identify complications quickly. These efforts significantly improve the quality of life and longevity of patients with diabetes.



Cancer Facts

Cancer, a group of diseases, is characterized by uncontrolled growth and/or spread of abnormal cells. Normal cells in the body grow, divide to make new cells, and die in an orderly fashion. Most cells have a limited life span and growth cycle in a specific tissue and only divide to replace dying cells or to repair injuries. Cancer cells have a unique ability to divide continuously without dying and can also grow outside their tissue of origin.

- ▶ Cancer is the second most common cause of death in the U.S.
- ▶ In 2015, about 589,430 Americans are expected to die of cancer, or about 1,620 people per day.
- ▶ About 1.7 million new cancer cases are expected to be diagnosed in 2015.
- ▶ Nearly 14.5 million Americans with a history of cancer were alive on January 1, 2014.
- ▶ The Agency for Healthcare Research and Quality (AHRQ) estimates that the direct medical costs (total of all health care expenditures) for cancer in the USA in 2011 were \$88.7 billion.

With the huge impact that cancer has on millions of Americans every year, the American Cancer Society recommends specific screening procedures for certain age and risk groups for early detection. Early detection provides clinicians more options in determining the best treatment paradigms, leading to more favorable outcomes and prognoses. Laboratory medicine is integral to the diagnosis, treatment, and monitoring in all types of cancer. Laboratory tests provide information for screening, diagnosis, distinguishing between cancer subtypes, and determining patient eligibility for targeted treatments.

The laboratory plays a central role in widespread screening for several cancer types, including cervical, colorectal and prostate cancer. Pap testing is recommended for women every 3-5 years, depending on age, to

Laboratory tests—including standard screens and targeted genetic tests—continually improve the quality of care for patients with cancer.

screen for cervical cancer. Men over 50 can choose to have a digital rectal examination and prostate-specific antigen test. Colorectal cancer screening is recommended every three to 10 years for men and women over age 50, depending on assessed risk. Several different laboratory tests are used in colorectal cancer screening, including fecal occult blood test, fecal immunochemical test, or stool DNA test, in addition to imaging studies.

In addition to screening for early detection, laboratory medicine also provides testing to guide treatment decisions and predict outcomes and, in some cases, to determine treatment eligibility. For example, in breast cancer, only patients with HER2 overexpression are eligible for treatment with trastuzumab, which has become

the standard of care for these patients. The addition of intravenous trastuzumab to treatment regimens has been shown to slow the onset of disease progression and to improve objective response rate, duration of response, and overall survival in HER2-positive breast cancer patients. Targeted screening for detection of mutations in BRCA1 and BRCA2 genes, which increase the risk of breast and ovarian cancers, is recommended for anyone with a family history of breast cancer. The results of these targeted screens inform and guide treatment options. Similarly in lung cancer, testing of EGFR mutations and ALK rearrangements is recommended in all patients with advanced stage adenocarcinoma to guide treatment with epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) inhibitors.

These advances in laboratory medicine significantly improve the quality of patient care by improving diagnosis and ensuring that patients receive the appropriate treatments to maximize clinical efficacy without unnecessary side effects. This contribution by clinical laboratory professionals is the benchmark essence of personalized/precision medicine, revolutionized with novel diagnostic and treatment procedures.



Infectious Disease Facts

Infections are illnesses caused by invasion of the body by disease-causing organisms such as bacteria, viruses, parasites, and fungus. Infectious diseases can cause acute or chronic illness and death. Infectious diseases are one of the leading causes of death worldwide.

According to the CDC, each year in the USA:

- ▶ 23.6 million physician office visits are recorded for infectious and parasitic diseases.
- ▶ Millions of people live with chronic hepatitis (including 700,000 – 1.4 million cases of hepatitis B and 2.7– 3.9 million cases of hepatitis C); 3,500 new cases of hepatitis A, 19,800 cases of hepatitis B, and 29,700 cases of hepatitis C are newly diagnosed and managed.
- ▶ More than a million new cases of sexually transmitted diseases are diagnosed, including 1.4 million cases of chlamydia, 334,000 cases of gonorrhea, and 49,000 cases of syphilis.
- ▶ 1.1 million patients are discharged after hospitalization due to pneumonia, with an average stay of 5.2 days and 53 deaths annually.
- ▶ 47,989 new cases of AIDS/HIV are diagnosed and 6,955 deaths occur due to AIDS and its complications.
- ▶ 30,831 cases of Lyme disease are discovered.
- ▶ 9,945 cases of tuberculosis are diagnosed.
- ▶ 3,697 deaths occur due to influenza.
- ▶ 2,000 cases of malaria are diagnosed and treated.
- ▶ 551 cases of meningococcal disease are managed.



Infectious Diseases

The Laboratory's Role

Infectious diseases can be acquired through travel, food, and contact with infected individuals and the environment. While the immune system can fight some infections through the production of antibodies and other mechanisms, many illnesses are caused by organisms that the body has never encountered and against which the person has not been vaccinated, making the immune response to these agents sluggish or even absent.

Just as infectious agents vary considerably, patients with infections tend to present with a wide variety of often vague symptoms, including fever, body aches, diarrhea, vomiting, and general malaise. Laboratory testing plays a

key role in identifying the cause of patient symptoms and in monitoring the care and recovery of patients with infectious diseases. The experts in clinical laboratories rapidly develop new tests in response to public-health emergencies in infectious diseases, such as the SARS, MERS, and Ebola epidemics.

through past immunization). Serology can also identify the specific cause of patient symptoms, for example by differentiating hepatitis A, B and/or C antibodies. Laboratory professionals continue to make strides in detecting and identifying infectious agents. Advances have minimized the amount of blood necessary to run the tests and have even reduced the number of instruments the laboratory needs to provide full-service testing. Newer molecular diagnostics can identify the specific strain of virus responsible for respiratory and diarrheal illnesses. The ability to rapidly develop new molecular testing has been instrumental in screening and containing recent emerging viruses, like H1N1, SARS, MERS, and Ebola. In fact, laboratory developed tests were critical in the identification and isolation of patients entering the U.S. during the recent Ebola epidemic.

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The specific approach to laboratory testing depends on the suspected infectious agent. In bacterial infections, cultures of blood and body fluids can identify the strain of bacteria, and susceptibility testing can help the physician select the optimal antibiotic for the patient's infection, individualizing treatment to both cure the infection and reduce drug side-effects. For viral infections, laboratory professionals use serologic tests to detect antibodies that signify exposure to infectious agents or immunity to certain infections (like hepatitis

Laboratory diagnostics are a vital component of the clinical care of patients with infectious disease, and laboratory medicine professionals continuously work with the clinical community to advance our ability to detect, characterize, and treat infectious agents.

Laboratory Medicine

The Future of Healthcare



The value of laboratory medicine is evident in its clinical and cost effectiveness, not only for the patient and individual clinician, but for the entire healthcare system and its myriad stakeholders. Through the diligence and dedication of clinical laboratory professionals, the field of laboratory medicine has evolved to enable high output tests to yield large numbers of bundled diagnostic results with enhanced efficiency and lower costs. Clinicians are now better able to diagnose and treat medical conditions earlier, even identifying the presence of risk for a disease before clinical symptoms are exhibited.

Laboratory professionals continue to strive to improve the efficiency, integration and sophistication of existing diagnostic models. Recent technological

advances in laboratory tests. Clinical laboratory professionals are at the forefront of developing new branches of diagnostics to meet the ever-changing needs of the healthcare system. Emerging targeted tests, such as pharmacogenomics assays and therapeutic drug monitoring, enable more patient-specific results and disease management capacity.

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The full realization of personalized medicine requires integration of clinical laboratory professionals into the healthcare team. Continued advances in laboratory medicine will allow physicians and patients to better assess the risks and benefits of care options and customized health management strategies to optimize individual health and quality of life.

and scientific advances in laboratory medicine, including the decoding of the human genome, have provided new tools for personalizing medical treatments.

The evolving field of personalized or precision medicine has the potential to transform clinical practice, and it relies heavily on



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