

STRENGTHENING LABORATORY CAPACITY



OVERVIEW

Laboratories are essential components of the health system and are critical in detecting and monitoring treatment for diseases, such as HIV and TB. The U.S. Centers for Disease Control and Prevention (CDC) is **world renowned for its leadership in strengthening public health laboratory systems** and networks. Through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), CDC supported more than 10,000 labs or testing sites in 2020 in more than 40 countries, enabling them to identify and prevent the spread of HIV, TB and other diseases that can threaten health and safety across the globe.

BUILDING TRUST IN THE SYSTEM: QUALITY IMPROVEMENT

Laboratory services are only as strong as the accuracy and timeliness of the results, which clinicians rely upon to deliver lifesaving interventions. **To build confidence and enhance trust in laboratory systems across the world, CDC developed and implements continuous quality improvement programs,** such as *Strengthening Laboratory Management Toward Accreditation*. It is a structured training and mentorship program supporting laboratory managers to achieve rapid and measurable improvement in laboratory quality and services using available resources.

CDC focuses on the interface between clinics and laboratories, focusing on the appropriate collection of patient specimens and efficient delivery of laboratory results to clinicians. The CDC-developed *Laboratory African Regional Collaborative* and the *Clinic-Laboratory Interface Continuous Quality Improvement* programs use proven continuous quality improvement methodologies. They strengthen coordination between clinics and laboratories, including sample collection, transportation to the laboratory, testing, result return to the clinic and client, and appropriate treatment to achieve better patient outcomes. **The sooner someone is aware of their HIV or TB status, the sooner they can be given effective treatment, and effectively eliminate**

transmission to others.

To increase enrollment and adherence, CDC laboratories support a patient-centered approach to HIV and TB services. This often requires diagnostic services delivered at or near the point-of-care – the time and place a patient receives care. To improve health outcomes, **CDC supports communities in implementing point-of-care testing programs** by providing *Rapid Testing Continuous Quality Improvement* training to increase the competency, efficiency, and productivity of testing staff.

CDC supports global normative bodies in establishing standards for high-quality and accurate test results. CDC is the only U.S.-based laboratory designated by the World Health Organization for performing HIV drug resistance testing to support national and subnational surveys to estimate the prevalence of resistance to key antiretroviral drugs. **CDC laboratories in the U.S. serve as reference facilities helping laboratories around the world** establish and enhance protocols and standards for testing, training, and continuous quality improvement.

EFFICIENCY AND SUSTAINABILITY: TEST EVALUATION, IMPLEMENTATION, AND OPTIMIZATION

CDC provides hands-on technical assistance, working closely with ministries of health and other laboratory partners to support high-quality training and build capacity. **CDC supports the sustainability and preparedness of national public health laboratory systems and diagnostic networks** by aiding in the development of National Laboratory Strategic Plans. CDC has contributed to the development of these plans in more than 40 countries.

As the only U.S. Government agency to serve as a World Health Organization HIV prequalification independent evaluation testing laboratory, CDC evaluates the operational and performance characteristics of new laboratory and point of care HIV viral load and early infant diagnosis molecular tests. CDC laboratories independently evaluate rapid HIV test kits, which deliver results at the point-of-care, for potential use in PEPFAR-supported countries to support timely,





EFFICIENCY AND SUSTAINABILITY: TEST EVALUATION, IMPLEMENTATION, AND OPTIMIZATION (CONT)

reliable, and high-quality HIV tests. Only 50 percent of rapid tests presented for evaluation have passed CDC's rigorous testing protocols, demonstrating the importance of quality assurance testing.

INNOVATIONS TO STAY ON THE CUTTING EDGE OF SCIENCE

CDC continues to develop innovative tools and techniques to support high-quality testing and timely delivery of accurate results in response to challenges in global settings, such as inconsistent electricity supply, transporting laboratory specimens over expansive and challenging terrains, and difficulties that clients face in accessing diagnostic and treatment monitoring testing services.

To identify geographical areas and subpopulations with HIV transmission and to target HIV prevention interventions, **CDC developed a low-cost rapid test that distinguishes between recent (within the last 1 year) and long-term HIV infections.** CDC has implemented this rapid test in 19 PEPFAR-supported countries with plans for additional countries in 2021.

CDC developed a HIV genotyping test to detect HIV drug resistance that costs significantly less to run per test than others. This test detects resistance to HIV medication and informs a switch, if necessary, to a more effective medication because drug resistance allows HIV to grow, increasing a person's likelihood of illness and possibly death. The HIV genotyping assay is now commercially available and used in drug resistance testing laboratories throughout the world. In 2020, CDC completed development of a new test to assist with monitoring the effectiveness of additional HIV medications, including Dolutegravir.

CDC is the only U.S. Government agency to assess the accuracy and reliability of rapid molecular TB test results used at the point of care.

To support sustainable programs, CDC actively transfers new technologies to country and regional providers.