



## *Building Laboratory Capacity*

A good public health laboratory network is a cornerstone of a strong response to HIV/AIDS. Without laboratory support, it is difficult to diagnose HIV infection and provide high-quality care and treatment for people living with HIV/AIDS (PLWHA). With the rapid expansion of HIV treatment in resource-poor countries, and the accompanying need for HIV diagnosis and associated care, there is a need to build capacity for high-quality laboratory services.

### **Building Laboratory Capacity and Supporting Quality Testing**

The U.S. President's Emergency Plan for AIDS Relief (Emergency Plan/PEPFAR) supports a diverse range of strategies for building laboratory capacity.

- **Laboratory quality assurance** is critical for making an accurate diagnosis of HIV infection and monitoring patients while on treatment. It also includes on-site supervision and monitoring to support laboratories in smaller facilities.
- **The use of rapid HIV tests** can dramatically expand a country's capacity to perform HIV testing. Rapid tests require minimal equipment and can be reliably performed by less experienced health care workers. Rapid tests are especially important in remote testing sites – those far from fully equipped laboratories.
- **Incidence testing** provides countries with data regarding where recent HIV transmission has occurred. This information is essential for planning effective prevention programs and for measuring the success of programs.
- **Tests for early infant diagnosis of HIV infection** are technically complicated and costly. The Emergency Plan promotes early infant HIV diagnosis through the use of dried blood spots. Dried blood spot testing allows medical staff to collect blood on laboratory paper. The samples are easy to transport and store, and the test can determine the HIV status of infants as young as six weeks old.
- **CD4 testing** is necessary for determining the level of immunosuppression in PLWHA. It is an important component in determining when to initiate treatment and for monitoring response to treatment.
- **Detection of resistance to ARVs** will become more critical as the number of individuals on treatment increases. PEPFAR works with the World Health Organization (WHO) to support its efforts to improve global, population-based surveillance for HIV drug resistance.
- **Diagnosing opportunistic infections**, including sexually transmitted infections, and referring patients for HIV counseling and testing is important not only for the treatment and care of patients, but also for the prevention of future HIV transmission.
- **Tuberculosis (TB) diagnosis and TB drug resistance testing** are vital, because up to half of all AIDS-related deaths are caused by TB. It is critically important to rapidly diagnose and treat people with TB in order to prevent illness and death, and to prevent the spread of TB to others.

President George W. Bush's Emergency Plan for AIDS Relief is the largest commitment ever by any nation for an international health initiative dedicated to a single disease -- a five-year, \$15 billion, comprehensive approach to combating the disease around the world.

*U.S. Department of State*

*U.S. Agency for International Development*

*U.S. Department of Defense*

*U.S. Department of Commerce*

*U.S. Department of Labor*

*U.S. Department of Health and Human Services*

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**Mailing address:  
SA-29, 2nd Floor  
2201 C Street, NW  
Washington, DC 20522-2920  
[www.PEPFAR.gov](http://www.PEPFAR.gov)**



## Key Components for Building Laboratory Capacity:

- Develop comprehensive, in-country laboratory policies, strategic plans and implementation strategies;
- Plan for and provide technical assistance to national laboratories;
- Facilitate communication between and among countries (including south-to-south technical assistance) regarding good laboratory practices;
- Provide technical review of laboratory activities, technical documents, papers and abstracts;
- Integrate good laboratory practices into strategies, technical guidance and technical assistance;
- Ensure coordinated laboratory technical assistance; and
- Integrate laboratory activities into prevention, treatment, care, and strategic information programs within each country.

## The Emergency Plan at Work

The following examples illustrate how PEPFAR works with host nations to support laboratory-related services:

- **In Botswana, Ethiopia, Kenya, Mozambique, Namibia, Nigeria, Rwanda, Uganda and Zambia**, programs to diagnose HIV infection in infants using dried blood spot samples were developed. For example, in Botswana, PEPFAR has helped the Ministry of Health to begin routine testing of all HIV-exposed infants by performing HIV polymerase chain reaction (PCR) testing on dried blood spots, which are collected at immunization visits at six weeks of age. Using a dried blood spot is an important technological advance, helping to address problems obtaining blood samples from babies, because blood can be taken from a simple heel or toe prick. Perhaps most importantly, the blood samples can be transported to a PCR testing laboratory without the need for refrigeration.
- **In Uganda**, the Joint Clinical Research Center (JCRC) has established four Regional Centers of Excellence to respond to the critical need for high-quality laboratory services. To create the Centers of Excellence, existing laboratories underwent extensive renovations. With PEPFAR support, JCRC built extensions, installed computers, improved data collection systems, and provided clinical furniture, secure drug storage facilities, and communication equipment. The renovated laboratories have the capacity to conduct the sophisticated tests required in antiretroviral treatment management and monitoring, and to perform diagnostic and monitoring tests for children. These Centers of Excellence act as regional training and quality assurance centers. JCRC has also established laboratory management teams, whose role is to monitor and ensure delivery of high-quality laboratory services at the regional centers.
- **In Botswana, Kenya, Namibia and Zambia**, guidance and technical support were provided for TB diagnosis and drug resistance testing. A training package was developed on TB smear microscopy - the test used extensively for TB diagnosis. In addition, new methodologies are being implemented in national TB reference laboratories, to build capacity for rapid detection of drug resistant TB. For example, in Namibia, consultants spent two months in-country providing technical support for TB culture and drug susceptibility testing at the central reference laboratory, and presenting regional and point-of-care training in TB smear microscopy.
- **In Lesotho**, a quality system was established to monitor all aspects of laboratory testing. The goals of this system are to ensure the quality of the overall process, to detect and reduce errors, to improve consistency between testing sites and to help contain costs. A Quality Manager was identified to implement this system in the Central Laboratory in Maseru and to execute a quality assurance (QA) plan for the country to include all district laboratories. The quality manager will audit district laboratories, make suggestions for improvement and implementation of quality systems and perform follow-up visits to continuously monitor progress in the district labs.
- **In Botswana, Kenya, Namibia, Tanzania, Uganda and Zambia**, the Emergency Plan supported the development of a rapid HIV test training package, and a plan for the integration of HIV rapid testing in HIV prevention, treatment and care programs. This training package has been customized by host nations and used to train hundreds of health care workers. For example, in Botswana, a PEPFAR-supported Training of the Trainers workshop was conducted, resulting in 35 individuals certified to perform rapid HIV test training. These trainers are now working with the Ministry of Health to train counselors and nurses to expand HIV rapid testing in Botswana.