Group A. HIV Diagnostics: expanding access to HIV testing, especially for ANC, VCT, pediatric diagnosis, PMTCT/PMTCT+, and blood safety

HIV diagnostics are essential for HIV prevention and care activities. In order to expand access to PMTCT, VCT and blood safety services proposed in The Emergency Plan, it is necessary to know which patients, clients, or donors are HIV-positive. This is not only important for making clinical decisions, and transitioning to appropriate care, it also creates an opportunity for delivery of prevention messages. Where high patient/client throughput prevails, as is the case with major hospital facilities and major blood transfusion services, EIA-based testing is desirable when it does not disrupt patient flow. Because of the difficulty of getting patients into clinics for testing and the resulting loss to follow-up when they must return for their results at a later date, rapid HIV testing with same day results are extremely necessary if the projected number of clients anticipated to receive services through The Emergency Plan are to be met. Programs will require a major commitment to improve HIV testing capability at both central and district levels. Because of the expansion of testing sites, the quality of test results becomes even more important. Achieving the goals of The Emergency Plan will therefore require a systems approach that would involve the development of general standards for laboratory testing, a strict adherence to the standards and a system to objectively document adherence to the standards.

General Recommendations:

- Each Emergency Plan country needs a national laboratory assessment and a 5-year strategic plan:
    - To address the specific situation and needs of that country
    - To provide a framework for advocacy and partnerships at the country level
    - To promote an ongoing coordination of effort
    - To promote in-country capacity building (e.g., laboratory management, resources, infrastructure, human capacity.
- Each laboratory needs sufficient laboratory personnel to support point-of-service rapid diagnostics.
- When laboratory resources are insufficient to support point-of-service rapid diagnostics, new laboratory staff, adjunct laboratory staff, and other health staff need to be hired and trained, under the supervision of senior laboratory staff
- WHO and CDC guidelines on rapid diagnostic tests and algorithms should be reviewed and updated
- Diagnostic algorithms at different levels of the health system need to be evaluated and monitored on an ongoing basis.
- Because laboratory issues and their implementation are fluid and constantly evolving, they require monitoring and evaluation as part of program support

Key Issues to address in a laboratory strategic plan:

- A plan for roll-out and support of both central and district level laboratories
- Equipment support

- Reagents and supply chain management
- Quality Assurance
- Certification of laboratory personnel
- Training of laboratory personnel, including:
    - Current
    - Pre-service
    - Development of new personnel
- Policy issues, including:
    - Who will be allowed to perform testing
    - What tests should be performed
    - At what laboratory level should key tests be performed
    - Necessity of adapting and updating laboratory guidelines as new technologies and resources become available
    - Necessity of responding to new issues

Essential laboratory tests needed for an HIV diagnostics program:

- General clinical diagnostics, i.e., rapid, same day testing using a 3-step sequential algorithm, for the following types of sites:
    - VCT centers
    - TB clinics
    - STI clinics
    - ANC clinics

  The specific rapid tests that make up the algorithm should be determined by a systematic national evaluation and consensus process.

- PMTCT/PMTCT+
    - Adult clinical
        - Rapid same-day HIV testing
        - CD4 testing to screen for appropriate care and treatment
    - Adult special program needs
        - Nevirapine (NVP) resistance monitoring
    - Pediatric testing:
        - Simplified early infant diagnosis (e.g., P-24 antigen testing) for clinical management and program impact evaluation
        - Evaluation and use of rapid enzyme immunoassay (EIA) testing beyond 15 months and post breastfeeding for final outcome evaluations
        - Continued need to have some polymerase chain reaction (PCR) capacity in-country as gold standard
        - Need to be able to do dried blood spot (DBS) testing

- Blood Banking and Blood Transfusion Services
    - Rapid testing for point of service blood transfusions
        - Discard blood based on one single positive

        - Refer patients with a positive test result for confirmatory testing and voluntary counseling and testing (VCT)

Levels of Laboratory System: Tests and Services Performed

- Central Laboratory
    - Rapid HIV-1 test
    - EIA
    - CD4 dual-platform
    - Western Blot
    - Nucleic Acid tests (NAT) for viral load
    - Specimen archiving
    - Reagent controls
    - Test confirmation and validation
    - National Quality Assurance program
- Intermediate (provincial) Laboratory
    - Secondary reference
    - Moderate Capabilities
    - Rapid HIV-1 test
    - EIA
    - CD4 simplified flow (FACSCount)
- Peripheral (district) Laboratory
    - Rapid HIV-1 test
    - EIA (if equipment already present)
    - Manual CD4 test
    - Provide quality assurance for point of care testing

First Year Plan

- Develop statement of purpose for rapid HIV-1 testing and CD4 testing
- Develop training plan and training curriculum for rapid HIV-1 testing and CD4 testing
- Develop assessment protocol
    - Checklists for each laboratory tier
    - Identify the person/team for assessment
    - Establish laboratory goals and indicators
- Identify and assess priority sites
- Determine plan for central test kit procurement (rapid HIV-1, EIA and CD4)
    - Bulk agreements
    - Distribution (with coordination of large donors)
- Procure laboratory equipment for central and district laboratories
- Identify and establish hierarchical “centers of excellence”
- Hire key expert personnel
    - National quality assurance leader
    - National quality assurance team members
- Hire in-country laboratory program advisor (US government-sponsored)
- Establish laboratory data management system

Second Year Plan

- Adopt statement of purpose at the national level
- Implement training at the national level
- Train and implement at least 50% of program sites
- Establish a system for monitoring and evaluating the program, completing the first report by the end of the second year

Critical tools and Products

- National guidelines for testing, including a menu of tests:
    - Rapid HIV-1 test
    - CD4 test
- National standard operating procedures for testing
- Training packages, including curriculum development
- National quality assurance and assessment plan
- Implementation plan
- Procurement, inventory, and distribution plan