



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pediatric Diagnosis: The Ethiopia Initiative

**Expanding Access to Pediatric HIV/AIDS Care
and Treatment in Ethiopia**

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Presentation Outlines

- Background
- Current Laboratory Activities
- Pediatric diagnosis - Implementation plan
- Developing and strengthening laboratory network

Laboratory Mandate in PEPFAR Program

- Provide direct quality support to National HIV/AIDS care treatment and prevention programs
- Assure minimal standards are met before high-end requests are filled
- Ensure service has impact at point-of-care
- Service is timely and responds to the epidemic
- Provide lab systems infrastructure – a platform to support expanded national programs

Infrastructure Development

- Renovation of National HIV/AIDS Laboratory and furnishing with equipments



Infrastructure Development

- Renovation of ART hospital laboratories
- Purchase Laboratory equipments for diagnosis and monitoring
 - National and regional Reference labs
 - ART hospital laboratories
 - Clinical chemistry, Hematology, FACS Count, Microscopes, Sterilizers, Fridge/Freezers,

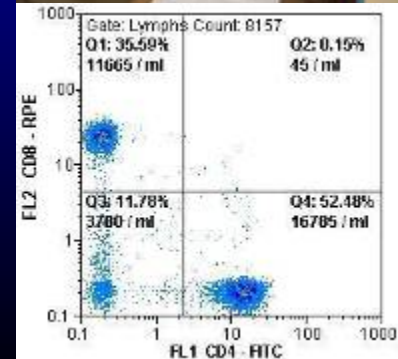
Laboratory Services

Individuals

- **Diagnosis of HIV infection (adults and children): VCT, blood safety, PMTCT, HIV care**
- **Determination of eligibility for ARV (E.g. CD4)**
- **Monitoring for ARV toxicity**
- **Diagnosis of TB,STI, malaria**

Programs

- **Surveillance**
- **Drug Resistance**
- **Quality Assurance**



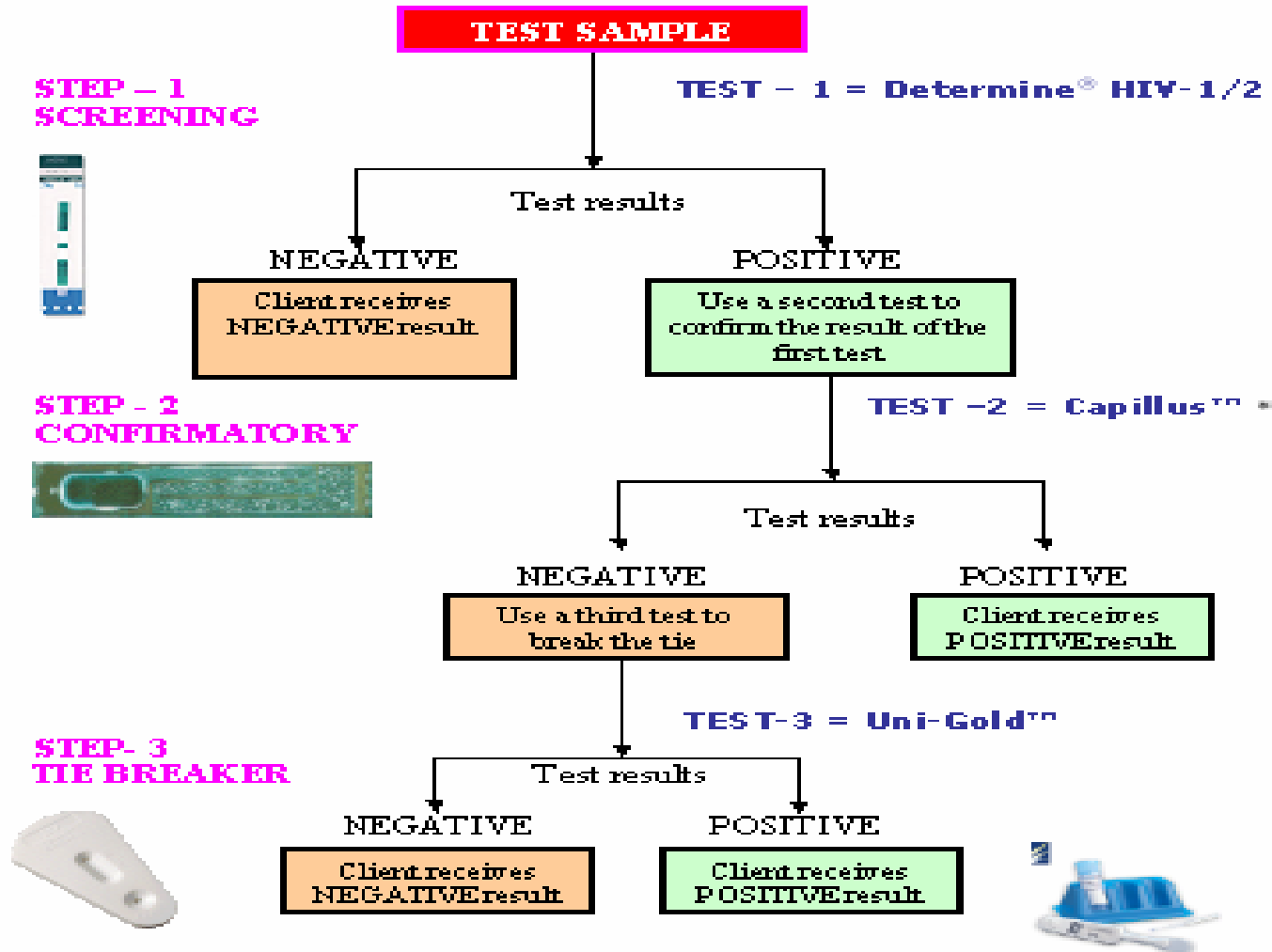
Laboratory Services

- Laboratory diagnosis of HIV infection: HIV Antibody test (Rapid test)
- Staging of disease progression, and monitoring of antiretroviral toxicities
 - CBC, differential, hemoglobin, etc
 - ALT, creatinine, Bilirubin, serum glucose, etc
 - Total lymphocyte
 - CD4 count
 - Viral load test (?)
- Services being provided at 30 ART hospitals

Technical support

- Evaluation of HIV test procedures
 - National HIV Rapid Test algorithm
 - DBS technology for surveillance and monitoring
 - HIV incidence test
- QA/QC program – improving quality of laboratory services

HIV RAPID TEST ALGORITHM



* In a setting where there is no refrigeration, Capillus[™] can be substituted with OraQuick[®]



Developed by the Ethiopian Health & Nutrition Research Institute in collaboration with the Ministry of Health and U.S. Centers for Disease Control & Prevention (CDC)



Technical Support

- Support hospital level laboratory capacity
- Rapid Testing: point-of-service for programs
- Diagnosis and monitoring
- Training - national, regional and site levels
- Follow up, onsite training and supervision

Pediatric HIV Diagnosis

- HIV serology
- HIV culture
- HIV-P24 Antigen
- HIV DNA or RNA PCR

Pediatric Diagnosis

Problems of Laboratory Tests

- **Because of the presence of maternal antibodies in children under the age of 18 months, serologic tests are not useful**
- **Enhanced HIV p24 assay is potentially useful, but remains to be validated**
- **Nucleic Acid Technology (NAT) based Assays could be useful in pediatric diagnosis: Standard PCR testing on whole blood, and dried blood spots (DBS) has been used**

Pediatric HIV Diagnosis

- Children $>$ 18 months of age
 - HIV antibody test: HIV Rapid Test
 - Follow the national HIV testing algorithm
- Children $<$ 18 months of age
 - Virologic test: DNA PCR test
 - Currently not provided

Establishing pediatric diagnosis

- Validate a nucleic acid based-assay for the diagnosis of HIV-1 infection in infants and young children
 - Whole blood and DBS
- Setting up HIV DNA PCR test
 - National HIV/AIDS laboratory, EHNRI
 - 6 regional laboratories
 - Addis Ababa, Adama, Awasa, Bahir-Dar, Mekele, Harar

Establishing pediatric diagnosis

- Procurement:
 - PCR machines (Applied Biosystem, Gene AMP 9700) and accessories purchased
 - Installation planned
 - Test kits

Establishing pediatric diagnosis

- Coordinate activities with ICAP-CU and EHNRI
 - Developing and validating diagnostic algorithm
 - Curriculum development and conduct hands on training
- QA/QC plan

Developing and strengthening a network of laboratories

- Plan to develop and strengthen a network of laboratories based on a tiered model of services.
- The national and Regional Reference laboratories as centers of excellence at that provide support, including quality assurance, to more remote health centers with limited laboratory capacity

National

Centers of Excellence
National Reference Lab, EHNRI
Referral Hospitals

Regional

Regional Labs
Regional/Zonal Hospitals

District

District Hospitals

Health Center

Health center, Clinic, VCT



Integrated Services and Testing



Policy and Strategic Planning

Functions that Create the Tiered, Quality-Assured Laboratory Network

- **National Standards of Training**
 - Technician / supervisor, Test performer
- **Constant Reagent Supply**
- **Guidance for Standard Operating Procedures**
- **Quality Assurance**
 - EQA (National – District – Health Center)
 - Regional / District Quality Assurance Package
 - Proficiency testing & observed performance

The Quality Assurance Cycle

