

# **Presentation delivered during the Technical Advisory Committee on HIV/AIDS/STI**

Boca Chica, República Dominicana  
22-24 January 2005



# Selection and Procurement of HIV/AIDS Diagnostics

PAHO Technical Advisory Committee on  
HIV/ AIDS  
January, 2005



# Outline

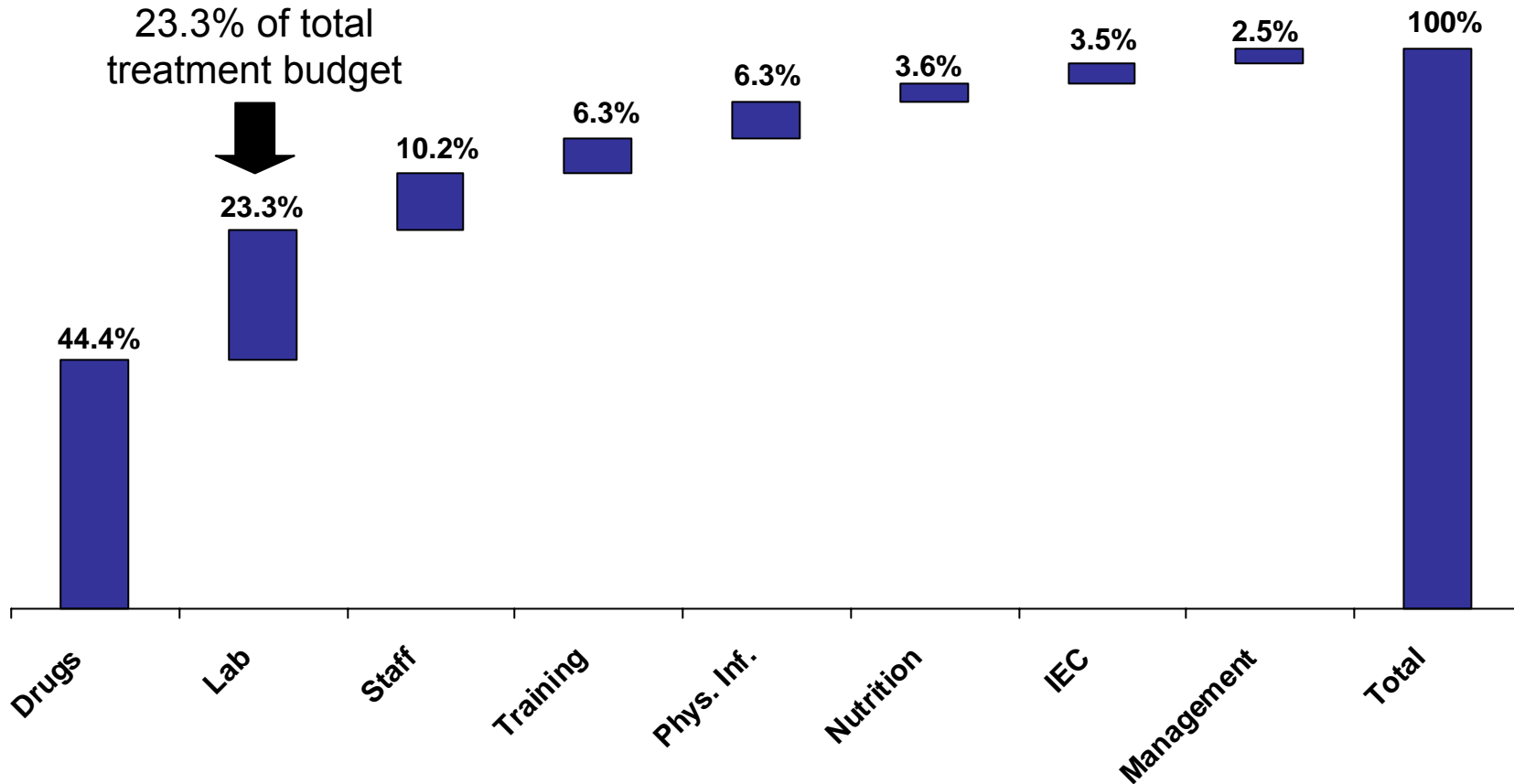
- Overview of HIV/AIDS laboratory testing
- HIV Screening algorithms and procurement options
- CD4 Testing algorithms and procurement options
- Viral Load Testing
- Other Tests, pediatric

# Cost of Lab Testing

## Treatment Budget – Country X

ILLUSTRATIVE

In Country X, lab costs constitute 23.3% of total treatment budget



Testing costs can be reduced with efficient and effective management

# Key principles of HIV/AIDS testing

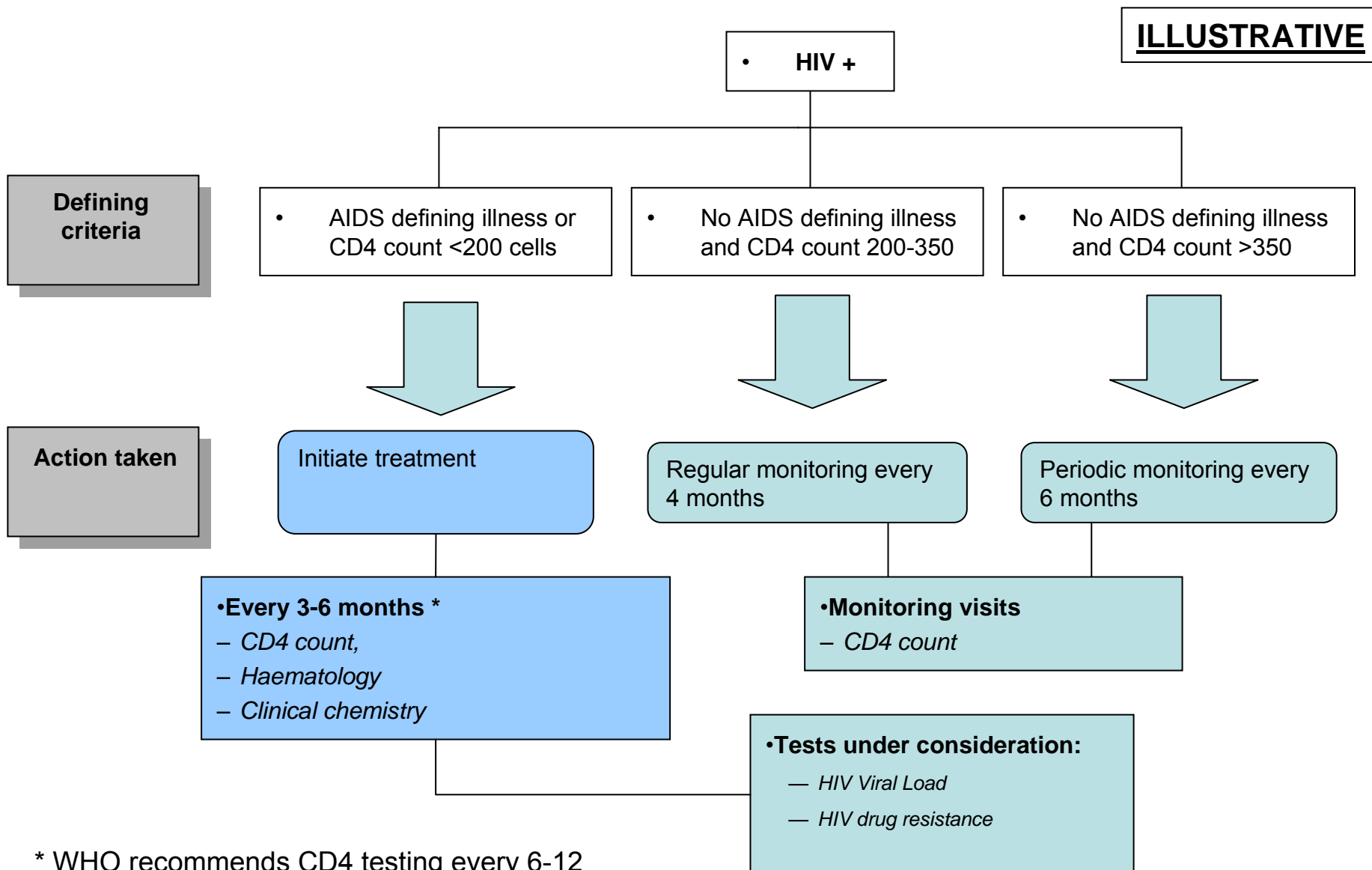
- An effective and efficient system for high quality lab testing is essential
- The testing should be reliable and cost-effective
- A systematic, well designed plan is needed to coordinate laboratory testing for the entire program
  - Collaboration of all treatment centers is essential in an integrated and sustainable plan
  - Development of standard protocols and algorithms
  - Different tests need to be conducted at different levels of the lab infrastructure
  - In many settings, high volumes of tests will ultimately need to be conducted
  - Testing capacity has to cater for a wide distribution of patients and clinical sites

# Laboratory tests in HIV care & treatment

- HIV diagnosis
  - Rapid test and ELISA in adults
  - DNA PCR test for children under 18 months
- Treatment eligibility for all HIV+ and monitoring for all on therapy
  - CD4 cell count
- Safety Assays for drug toxicity for all treated patients
  - Clinical chemistry and hematology
- Standard of care tests in routine clinical practice
  - STI and opportunistic infection diagnosis, e.g. TB
- Special consideration tests and for monitoring and evaluation
  - Viral load
  - Drug resistance

# Lab protocol for care and treatment

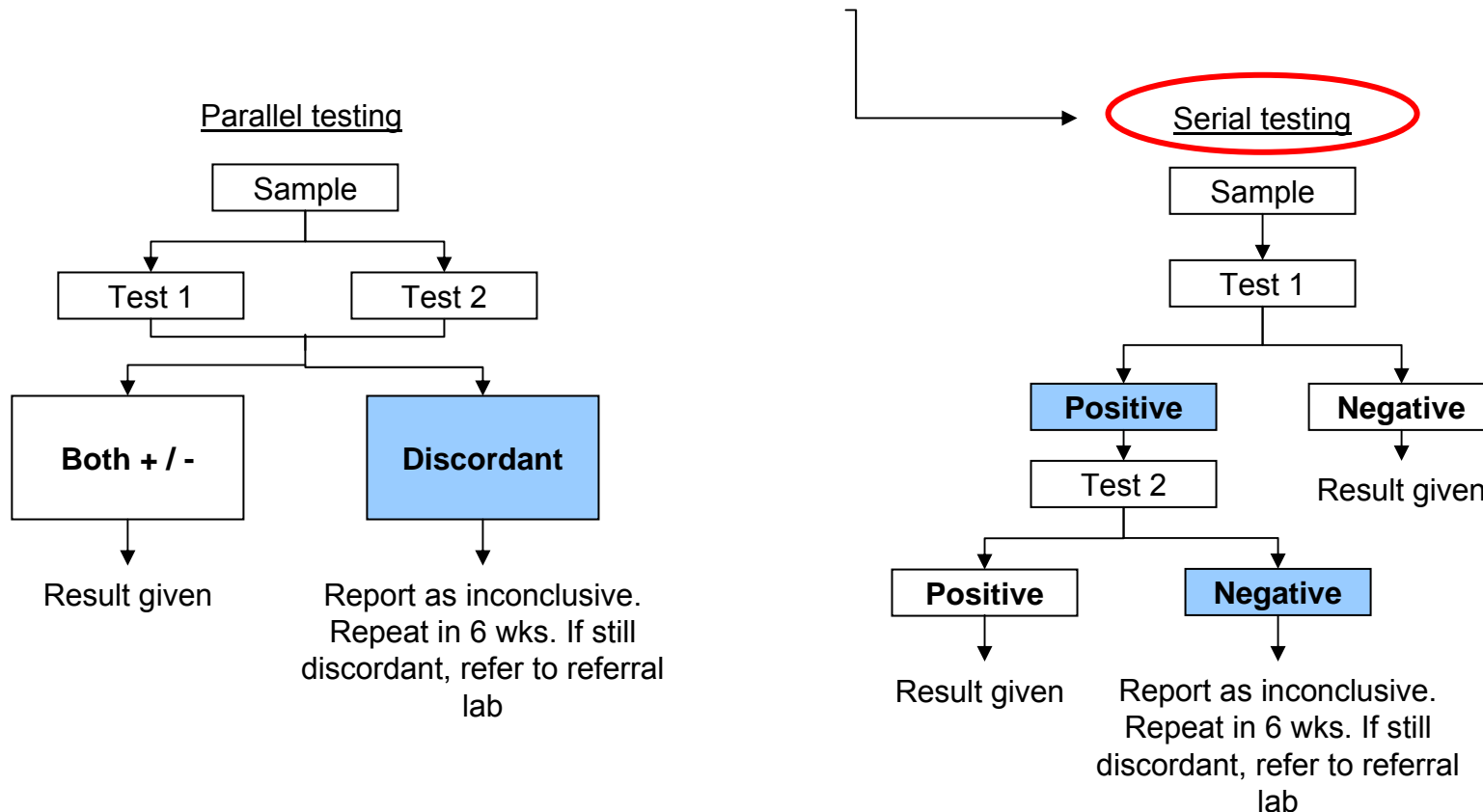
**ILLUSTRATIVE**



\* WHO recommends CD4 testing every 6-12 months for patients on ART;

# Screening testing algorithms

- WHO recommends serial testing: Greater cost efficiency, comparable accuracy



# Options for Diagnostic Testing

## WHO recommends the use of rapid tests as the primary diagnostic:

- Same-day results
- Reduced cost: lower cost per patient receiving results
- Ease of Use
  - Can be performed by trained health workers and does not require laboratory technicians or infrastructure
  - Results are easy to interpret
- Allows for decentralization of testing
- Allows for testing of individual specimens

	<b>ELIZA</b>	<b>Simple/ Rapid Tests</b>
Detection	•HIV antibodies in plasma/ serum	•HIV Antibodies in whole blood or plasma/serum
Accuracy	•Varies with test but similar performance	
Lab Equip./ Personnel	•Micropipette, washer, incubator, spectrophotometer •Skilled technician	•Micropipette •Trained health care worker
Time to Result	•> 2hours	•10 -30 minutes

# Test kit procurement options

	WHO HIV Test Kit Bulk Procurement Scheme	Abbott Access	Clinton Foundation (forthcoming)
<b>Products</b>	<ul style="list-style-type: none"> <li>• ELISAs</li> <li>• Simple/Rapid assays</li> <li>• Confirmatory assays</li> <li>• Total 22 tests</li> </ul>	<ul style="list-style-type: none"> <li>• Determine® HIV-1 / 2 (rapid test)</li> </ul>	<ul style="list-style-type: none"> <li>• Abbott Determine®</li> <li>• Trinity Biotech</li> <li>• Organics</li> <li>• Other WHO-evaluated rapid tests</li> </ul>
<b>Price (USD)</b>	<p>Average prices of product range:</p> <ul style="list-style-type: none"> <li>• ELISA \$0.27-1.20</li> <li>• Simple/Rapid \$0.47-2.60</li> <li>• Plus freight and other charges</li> </ul>	<ul style="list-style-type: none"> <li>• \$0.80 for LDCs</li> <li>• Plus freight, insurance, customs handling, taxes/duties, cost of product distribution to facilities</li> </ul>	<ul style="list-style-type: none"> <li>• TBD</li> </ul>
<b>Quality</b>	<ul style="list-style-type: none"> <li>• WHO quality evaluation</li> <li>• Evaluated annually</li> </ul>	<ul style="list-style-type: none"> <li>• WHO quality evaluation</li> </ul>	<ul style="list-style-type: none"> <li>• WHO quality evaluation</li> </ul>
<b>Eligibility</b>	<ul style="list-style-type: none"> <li>• Member states</li> <li>• WHO partner NGOs</li> <li>• Donor-supported HIV projects; others</li> </ul>	<ul style="list-style-type: none"> <li>• LDCs (UN)</li> <li>• African countries</li> </ul>	<ul style="list-style-type: none"> <li>• CF partner countries and Procurement Consortium</li> </ul>

# CD4 procurement options

High Throughput  
~300 tests/day  
~80,000/year

Low Throughput  
~ 30-50 tests/day  
~10,000/year

**Becton  
Dickinson  
(BD)**

## **FACS CALIBUR** \*

- CD3, CD4 & CD8
- Provides absolute count & % (pediatrics)
- Automatic loading
- 1 technician/150 samples
- Automated data management

## **FACS COUNT** \*

- CD3, CD4 & CD8
- Provides absolute count only.
- Doesn't measure % (pediatrics)
- Manual loading/efficiency dependent on staff competency
- 1 technician/30 samples

**Beckman  
Coulter  
(BC)**

## **EPICS XL** \*

- CD4, CD45
- Provides absolute count & % (pediatrics)
- Automatic loading
- 1 technician/150 samples
- Automated data management

## **POINTCARE** \*

- CD4, CD45
- Provides absolute count & % (pediatrics)
- 1 technician/28 samples

\* Clinton Foundation pricing available



New technology in pipeline:

- Point-of-care diagnostics – e.g. LabNow, CD4Now

# Rental vs. Purchase agreements

	<b>Reagent rental/ lease</b>	<b>Instrument/ reagent purchase</b>
<b>Terms</b>	Vendor supplies the instrument, reagents and service in one per-test cost	MoH buys instruments and assumes responsibility for consumables and maintenance
<b>Pros</b>	<ul style="list-style-type: none"> <li>•Immediate savings: lower upfront investment</li> <li>•Ongoing savings: lower per test price with all-inclusive price</li> <li>•Flexibility to respond to changes in technology</li> <li>•Ensures that instruments are serviced and maintained; transfers responsibility from MoH to supplier</li> <li>•Supplier is responsible for reagent supply</li> </ul>	<ul style="list-style-type: none"> <li>•Ownership of equipment</li> <li>•Familiarity with process</li> </ul>
<b>Cons</b>	<ul style="list-style-type: none"> <li>•No ownership of equipment</li> </ul>	<ul style="list-style-type: none"> <li>•Higher overall costs</li> <li>•MoH responsible for costs and logistics of service and maintenance after warranty period</li> <li>•MoH responsible for reagent supply to minimize machine down-time</li> </ul>
<b>CF options</b>	<ul style="list-style-type: none"> <li>•BD FACSCalibur, FACSCount</li> <li>•BC Epics XL, PointCare</li> </ul>	<ul style="list-style-type: none"> <li>•BD FACSCalibur, FACSCount</li> <li>•BC Epics XL, PointCare</li> </ul>

# Things to Consider

- Testing quality
- Instrument Maintenance & Repair
- Total Cost of Ownership
- System Flexibility – new technology in pipeline
- Infrastructure requirements
- Leasing vs. buying
- Centralized vs. decentralized testing
  - Technical choices
  - Pricing (pricing based on machine utilization)
  - Other costs (lab tech time/ training, consumables, sample handling)

# Viral Load procurement options

## **Abbott**

### **LcX HIV RNA QUANTITATIVE**

- Plasma
- Amplifies HIV-1 Group M (subtypes A-G) and Group O
- 21 tests/run

## **Bayer**

### **VERSANT SYSTEM 340**

- Plasma
- Amplifies HIV-1 Group M
- 12-168 tests/run
- **CF pricing available**

## **bioMerieux**

### **NUCLISENS EASYQ**

- Plasma, serum, **dried blood spots**
- Amplifies all HIV-1
- 48 tests/run
- **CF pricing available**

## **Roche**

### **AMPLICOR**

- Plasma, dried blood spots
- Amplifies all HIV-1, some HIV-2
- 9-48 tests/run
- **CF pricing available\***

Pricing: \$20-\$125/ test depending on supplier, volume and recipient country



New technology in pipeline:

- bioMerieux Nuclisens Automated Magnetic Extractor (forthcoming 2005 with CF pricing)

# Other tests

- STI and OI diagnosis
- Safety assays – chemistry and hematology
- Drug resistance surveillance and monitoring
  - WHO recommends implementing sentinel surveillance to detect resistance at population level
  - Consider developing capacity for resistance genotyping at regional/national level
- Pediatric tests
  - Diagnosis: HIV DNA PCR in children <18 months; or HIV RNA assay, immune-complex dissociated p24 antigen
  - Monitoring: CD4%; or lymphocyte count when CD4 is unavailable