# CD4 LABORATORY ASSESSMENT TOOL

## I. Basic information on the country to be assessed

1. The name of country:

2. Population:                    Rural population =       %

3. HIV Prevalence:

4. ART Target Goals for 2005 - 2008:

5. Number of Laboratories performing CD4 testing:
   **Please locate all labs by type (public, private, NGO, University) on Country map.**



6. Overall workload for cases (2004)

| Name of the Laboratory | Location City, Province | Kind of Lab<br>University (U)<br>Reference Lab (RL)<br>Regional Hospital (RH)<br>District Hospital (DH)<br>NGO (NGO)<br>Other International Organizations (IO) | Type of equipment | Technology used for CD4 Testing (single platform, dual platform, or Manual testing), and name of the test. | No. of test Performed per Month |
|---|---|---|---|---|---|
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## 2. Structural and functional profile of the laboratory network for the NTP

CD4 laboratory services should be organized taking account of accessibility to entire treatment population and provision of all the necessary services for efficient HIV case-management. ARV monitoring laboratory services are integrated into the general health system or provided by completely independent organizations at all or certain levels.

What is the model for the laboratory network:  centralized or decentralized?

How are samples transported within the laboratory network?

(1)  Structural profile

| | | Administrative levels (insert name of administrative unit if it is not applicable) | | |
|---|---|---|---|---|
| | | **National** PEPFAR    non-PEPFAR* | **Regional** PEPFAR    non-PEPFAR* | **Local** PEPFAR   non-PEPFAR* |
| No. of health institutions for HIV diagnosis & treatment | | | | |
| No. of laboratories | | | | |
| No. of laboratory staff at this level | MD/PhD | | | |
| | Technicians | | | |
| | Other workers | | | |

**\*Include all NGO labs, university labs, private labs and other international institution labs**

(2)  Policy

Is there a national guideline or SOP for CD4 testing?  If yes, is the guideline/SOP available at all laboratory sites?

Are there international partners involved in the country laboratory development plans, such as WHO, Global Fund, World Bank, etc?

Who is the main TRACK 1.0 partner in country?  Who coordinates their activities?  What part of the laboratory effort do they provide? (renovation, procurement, training, QA, etc)

Comments: _____

_____

## 3. Method and system for implementation of quality assurance

(1) Is there a national guideline (or protocol) of quality assurance for CD4 testing?

Is there a national reference lab for CD4 testing?

Name of Laboratory: _____

Laboratory Contact: _____

Describe reference lab personnel. (education and experience)

(2) Describe measures of quality control for CD4 testing?

(3) Describe the methods and system of external quality assessment (EQA) CD4 testing? (EQA is a process to assess laboratory performance by outside agency and includes On-site evaluation, Panel testing, and Blinded rechecking.)

Do Country laboratories participate in an international EQA program?

Is a report available for review?

How many laboratories participate in survey?

(4) Are supervisory visits made to laboratories in the field?

Please describe.

Is supervisory visit (on-site evaluation) carried out with a check-list? If so, attach it. If not, what points are checked during supervisory visit?

Describe the mechanism for feedback of the results of EQA or onsite supervision. (*at the intermediate level and national laboratories visited*)

Are there mechanisms to ensure that corrective actions (QI) are taken and sustained after the feedback? (*at the intermediate level laboratories visited*)

### 4. Laboratory  workload analysis

(1) Volume of work done at different levels (2004)

| Level of laboratory (rename, if necessary) | Number of CD4 Tests |
|---|---|
| National | |
| Regional | |
| Provincial | |
| Total | |

### 5. Safety

(1) Any training of safe laboratory practices?

(2)  Is there a laboratory policy covering blood and serum post-exposure prophylaxis?

(3) What is system for disposal of contaminated waste and sharps?


## 6. Human resource development

(1) Is there a national training plan for CD4 testing? (describe and attach a copy.)

(2) Give details of training of laboratory staff.  Consider, pre-service and in-service training, and the various levels of service (central, intermediate and peripheral).
Who provides the training?
Where is it conducted?
How often is it conducted?
How long is the training?
What is the curriculum (attach)?
Are there training facilities and what equipment are used?
Describe the training materials available e.g. laboratory manual? training modules?
Do these reflect actual practice?

(3) Approximate proportion of laboratory workers receiving refresher training each year.

(4) Describe the number and status of educational institutions for laboratory workers.

(5) Approximate number of technicians newly available in a year.

(6) Describe turnover rates of laboratory staff at central, intermediate and peripheral levels.

(7) Describe the unmet resource requirements for human resources development, 2004 – 2005 at central, intermediate and peripheral levels.


## 7. Procurement and distribution of supplies and equipment

(1) Is there a plan for the procurement and distribution of supplies (laboratory reagents, consumables etc.) and equipment (FACS Count, FACS Calibre, etc.), 2004 - 2005 (if yes, attach)?

(2) Does the Reference Laboratory take part in the procurement system?

(3) Describe the system for procurement and distribution.

(4)  What is budget for procurement and distribution of supplies and equipment, 2004 and 2005. Consider central, intermediate and peripheral levels separately (attach)?

(5) Who is responsible for procurement of supplies and equipment at central, intermediate and peripheral levels and what criteria are used in this process? Describe the system of recording and reporting for the status of supplies and equipment within the laboratory

system.  Is a standard form used (attach).

(6) Have there been interruptions to laboratory work at central, intermediate and peripheral levels due to shortages of supplies and equipment?

   If yes, please explain.

(7)  What mechanisms are in place to prevent interruption of work due to shortages of supplies and equipment?  If there is a policy to keep a buffer stock of supplies and equipment, describe.

(8) Describe the calibration and maintenance system for equipment.

(9) Is the provision of supplies and equipment at different levels of the laboratory system appropriate for the functional activities of laboratories at these levels? If no, why not?

## 8. Data management

(1) Is a standard laboratory register book in use?  (if yes, attach one)

(2) Is a standard laboratory request form in use? (if yes, attach one)

(3) On average, how often do laboratories report results to the clinic/hospital or physician?

(4)  On average, how long does it take for the laboratory report to be produced after the clinic has sent the patient or specimen to the laboratory (turnaround time)?

(5) How often do laboratories report on their performance (monthly, quarterly, 6-monthly or annually) and to which authorities do they send their reports?   Are there standard reporting forms (if yes, attach one each)?

(6) How is feedback to and from laboratories received from supervisors and how are records on supervision kept (e.g. are notes of the feedback kept)?