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Functions and Minimum Standards for National Reference Laboratories in the SADC Region

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ENGLISH

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Table of Contents

ACRONYMS AND ABBREVIATIONS

AIDS	Acquired immunodeficiency virus
ART	Antiretroviral therapy
EIA	Enzyme immunoassay (synonym ELISA)
ELISA	Enzyme-linked immunosorbent assay (synonym EIA)
HIV	Human immunodeficiency virus
IATA	International Airline Transport Association
MDR	Multidrug-resistant
MDG	Millennium Development Goals
MTCT	Mother-to-child transmission (of HIV)
PCR	Polymerase chain reaction
RDT	Rapid diagnostic test
SADC	Southern African Development Community
SNRL	Supranational reference laboratory
TB	Tuberculosis
VCT	Voluntary counselling and testing
WHO	World Health Organization
XDR	Extensively drug-resistant

1. INTRODUCTION

Communicable diseases, which are relatively controlled elsewhere, remain major causes of morbidity and mortality in the SADC. The major challenges are posed by the big three HIV and AIDS, tuberculosis and malaria. While SADC Member States contribute 5% of the world population, they account for more than one third of people living with HIV and AIDS in the world. The associated morbidity and mortality burden is disproportionate to population numbers and outstrips available resources.

Almost half (45%) of deaths associated with AIDS worldwide were reported within the SADC region. This is compounded by co-infection with tuberculosis (TB). Average notification rates for TB in SADC Member States exceed 400 per 100 000 population, compared with the global average of 139/100 000 (SADC, 2008b). The SADC TB prevalence estimates are four-fold higher than the Millennium Development Goal (MDG) targets for 2015. Alongside AIDS and TB there is the perennial burden of malaria. An estimated 90% of the global malaria burden is in sub-Saharan Africa. In addition, emerging and re-emerging diseases add to the burden on health. These include episodic resurgences of Ebola, recent cholera challenges and exposure to the global pandemic of influenza A H1N1. Communicable diseases continue to exert pressure on the human and financial resources of the region, and stifle development.

The management of communicable diseases starts with the identification of the causative agent of a condition, with laboratory diagnostics the cornerstone. This triggers downstream interventions, including therapeutics, treatment monitoring, epidemiological surveillance, population-wide disease control and preventive vaccine development. The diagnosis and management of communicable diseases requires laboratory services, buttressed by an enabling policy framework. Lower level laboratories are guided by the national reference laboratories, which tend to have better human and infrastructure resources. Laboratory services should provide accurate diagnosis leading to prompt and appropriate treatment, and they should support treatment monitoring. In the case of TB, sputum smear microscopy identifies M. tuberculosis bacilli without differentiating MDR from non-MDR.

The accurate diagnosis of multidrug-resistant (MDR) or extensively drug-resistant (XDR) TB allows for targeted and appropriate treatment, reduces morbidity, reduces mortality and is cost effective. At population level, it also facilitates public health surveillance, contact tracing and case hospitalisation, all of which can reduce the risk of the disease spreading locally and across borders.

Within Member States, National Reference Laboratories are at the pinnacle of diagnostic service provision. They play pivotal roles in the diagnosis, disease surveillance and statistical analysis of epidemiological data. The SADC Protocol on Health presupposes the existence and functional competence of these laboratories in its call for Member States to “cooperate in case definitions, notification systems, the treatment and management of the major communicable diseases”. When the roles and functions of national reference laboratories are well defined, their contribution to efforts to address the health challenges posed by communicable diseases in general and HIV, TB, malaria in particular is easier to anticipate.

This report sets out the minimum standards for national reference laboratories that must be achieved and maintained by all Member States. The functions and the standards that are outlined are applicable to the laboratories in general and address communicable diseases, with a specific focus on the “big three”: HIV and AIDS, TB and malaria.

2. CURRENT STATUS OF NATIONAL REFERENCE LABORATORIES IN THE SADC REGION

The SADC secretariat assessed the capacities of national reference laboratories to fulfil their functions. The assessment covered 14 Member States and was conducted between December 2008 and March 2009, when laboratories selected by Ministry of Health officials were visited.

The areas of assessment included generic issues that would affect laboratories regardless of their specialties (such as policy), as well as those specifically affecting the capacity to provide diagnosis and treatment monitoring for HIV and AIDS, TB and malaria. The results of the assessment were reported *(see the Assessment Report on the Current Status of National Reference Laboratories in the SADC Region, 2010).*

The assessment noted variations in the definitions of national reference laboratories. In a group of Member States, tertiary hospital-based referral laboratories were described as national reference laboratories; in others national public health laboratories were the national reference laboratories. In addition, some Member State laboratories were a hybrid of the two general profiles. There was no common denominator. The functions and roles of these institutions varied as did their staff composition and service profiles. The infrastructure housing the laboratories was variable.

The laboratory focus could be generally described as either diagnostic or public health, with the diagnostic profile predominating. In a smaller number of Member States the public health role was more prominent. Even when the laboratories were predominantly diagnostic or public health-oriented, the activities conducted within them varied widely between Member States. This was influenced in part by the staff composition. Factors explaining the variations included differences in the purposes for which the laboratories had been established originally. The intended purpose of the laboratories dictated the composition of personnel, equipment complement and the scope of services provided. Because the profiles were different, the perceived roles and functions were different. The expectations of policy makers and other laboratory users were defined by the profiles and functional capacities of laboratories within their Member States. Specific programs such as HIV and AIDS, TB and malaria tended to have more defined expectations. When the existing laboratory services did not meet these expectations, parallel laboratory services had been established in some cases. This tended to weaken the national reference laboratories and led to a segmented rather than general development of laboratory services.

Laboratories with a diagnostic bias in general had limited capacity to participate in public health activities. Likewise laboratories with public health profiles had inadequate capacity for the provision of diagnostic services. In addition to general challenges, diagnostic type national reference laboratories had a limited capacity to provide essential but specialised, sophisticated or costly laboratory tests. Key diagnostic tests (including the capacity to detect resistance to HIV and TB medicines) were not always available, even though the laboratories had predominantly diagnostic biases. Public health-type services were virtually absent in diagnostic type national reference laboratories. On the other hand, public health-type laboratories had inadequate diagnostic capabilities. Core, but discipline-neutral laboratory functions (such as human resources development and quality management) did not fall within the remit of either laboratory profile and were inadequately implemented.

Some of the shortcomings could be traced to the policies that had led to the establishment of the laboratories. These, for example, had not fully anticipated the public health roles. Consequently, the staffing norms did not include personnel capable of effectively carrying out disease surveillance and epidemic preparedness. As with the staffing norms, the logistics were not catered for and financial resources were not allocated.

A majority of the laboratories, regardless of their profile, experienced common and recurring gaps. These related mainly to policies and policy implementation plans, the numbers and expertise of personnel, attention to quality management, inadequate systems of information management and financial constraints. Financial limitations influenced the acquisition and servicing of equipment and the procurement of laboratory reagents, consumables and sundries. The challenges facing national reference laboratories are systemic. The optimisation of their functions requires a common redefinition of the expected roles, functions and minimum standards. These should be complemented with adequate allocations of appropriate human resources, operational logistics and financial support.

3. PURPOSE AND SCOPE OF THE DOCUMENT

The *SADC Protocol on Health* urges Member States to cooperate in various areas of health, including the management of communicable diseases. There is a drive by SADC to harmonise the operations of laboratories in Member States. This is encapsulated in the *SADC Protocol on Health*, Article 9 of which calls upon Member States to cooperate with respect to case definitions and notification systems, as well as in the treatment and management of the major communicable diseases. Key areas for collaboration rely on laboratories. However, there is no common denominator describing national reference laboratories. Differing understandings of their roles and functions are not conducive to harmonisation. The purpose of this report is to outline a common denominator that describes the roles that should be carried out by national reference laboratories. The *Protocol on Health's* call for Member States to "co-operate in the establishment of regional reference laboratories and in sharing technical expertise" is best realised on the basis of a common yardstick.

This report provides guidelines on the roles which national reference laboratories are expected to perform, and recommends certain minimum standards, which the laboratories should achieve and maintain. In outlining the roles, functions and minimum standards of national reference laboratories, the report proposes benchmarks as a basis for achieving common definitions of these laboratories. The report should provide Member States with a reference template that provides guidance as they seek to strengthen their diagnostic and public health capacities, and pursue the harmonisation of services.

4. JUSTIFICATION FOR DEFINING THE ROLES AND MINIMUM STANDARDS FOR NATIONAL REFERENCE LABORATORIES

Laboratory services in SADC Member States have historically been perceived to be weak. Global (United Nations Millennium Development Goals) and continental (Abuja Declarations of the African Union) targets for improving the care and support of people affected by communicable diseases depend on effective laboratory service provision. Weaknesses in laboratory systems therefore can be major bottlenecks.

SADC Member States have also addressed such concerns at regional level and within the broader context of the WHO African region. Some of the SADC laboratory initiatives are included in disease-specific strategies, such as the *HIV and AIDS Strategy, the Strategic Framework for TB Control including MDR/XDR in the SADC Region 2007-2015, and the Malaria Elimination Framework and the Malaria Action Plan.* Other aspects of SADC interventions are included in the *SADC Protocol on Health* (2004) and in the Regional Indicative Strategic Development Plan, and were addressed by SADC Ministers of Health during their meeting in Maputo in September 2006. These remain agenda items for future Ministerial meetings.

The WHO-AFRO Member States have also recognised that the initial steps in strengthening disease surveillance should involve the development of well-staffed and properly equipped laboratory services *(WHO-AFRO resolution AFR/RC43/R7 of the Regional Committee 53, 1998)*. The concerns of Member States prompted further initiatives ten years later. Deliberations aimed at reaching a consensus on clinical laboratory services, their harmonisation and standardisation were held leading up to the Maputo declaration. Later in the same year, the 58th session WHO AFRO meeting in Yaoundé, Cameroon *(58th Session of the WHO/AFRO Regional Programme Management, September 2008 Yaoundé, Cameroon)* passed a resolution on laboratories. The resolution recognised the inadequacies of laboratory services delivery and proposed measures to remedy the situation. The inadequacies included:

- The lack of laboratory policies and the absence of strategic plans for their implementation;
- Weaknesses in laboratory leadership;
- Deficiencies in public health service provision; and
- Limited quality management practices.

Addressing these challenges requires a common definition of how the laboratories should be structured and resourced as well as a common understanding of the services they should be providing.

5. PROCESS FOR DEVELOPMENT OF THE REGIONAL MINIMUM STANDARDS

The process for the development of this regional minimum standards was participatory including Member States, the SADC Secretariat and various stakeholders. The process was also informed by internationally-recognised best practices,

Firstly, a desk review of the current national, regional and global policies relevant to national reference laboratories was conducted. This was followed by individual country assessments in each Member State, during which key informants within the respective programs, including development partners, were consulted to provide information on the state of programmes and policies. The respondents also shed light on some challenges and best practices. Each visit culminated in a country level assessment report which was reviewed and validated by officials from Ministry of Health of each Member State. The country reports were then compiled to inform a regional picture of the situation and response analysis. The draft regional assessment report was used as a basis for Regional Minimum Standards. Both the draft Regional assessment report and the draft regional minimum standards were then reviewed by a technical team for technical soundness on 7-8 May 2009 at Windhoek, Namibia. The team comprised Member States, Technical Partners, and the SADC Secretariat. The purpose of the review team was to strengthen the quality of the documents.

Following the technical review and the incorporation of the comments, the documents were then presented to a regional workshop for validation of the situation and response analysis report and consensus building on the proposed regional minimum standards. All Member States and major stakeholders including regional partners and civil society organisations were invited to the validation and consensus building workshop. The workshop was held on 4-6 August 2009, in Gaborone, Botswana. The meeting recommended the draft reports for approval through the SADC structures subject to the incorporation of suggested changes.

Accordingly, the revised reports were reviewed by the CD Project Steering Committee at their meeting in September 2009 for technical soundness and recommendation for approval by Ministers. Finally, the document was reviewed by Senior Officials in Ministries of Health and those responsible for HIV and AIDS before being submitted for approval by the joint ministerial committee of Ministers of Health and those responsible for HIV and AIDS. The document was approved by the joint ministerial committee held in November 2009 in Ezulwini, Swaziland.

6. FUNCTIONS OF NATIONAL REFERENCE LABORATORIES

The roles of national reference laboratories can be divided into two complementary components: diagnostic and public health. Diagnostic laboratories are tasked with testing clinical samples in order to confirm or exclude abnormalities or diseases. This service is predominantly delivered in hospital or clinical settings. The scope of testing services ranges from the routine to the rare. The diagnosis of rare, costly or human resource intensive conditions is primarily and often solely conducted in national reference laboratories. These laboratories are positioned at the peak of the diagnostic pyramid in Member States, and are expected to serve as the ultimate diagnostic authorities. It follows that they should be staffed, equipped and resourced accordingly in order to fulfil these duties.

The public health functions of national reference laboratories focus on providing disease intelligence surveillance on the basis of which public health interventions can be planned. Diseases of public health importance include communicable diseases such as HIV and AIDS, Tuberculosis (TB), malaria, cholera, poliomyelitis and meningitis. Public health laboratories complement Ministries of Health in disease surveillance, epidemic preparedness and response. The two national reference laboratory roles converge when communicable diseases result in infections and require both continued surveillance and clinical management – as is the case with HIV, TB and meningitis.National reference laboratories provide services that are specialised and superior to those available in the national laboratory network. The national reference laboratory participates in the formulation of laboratory policy and is responsible for the coordination of policy implementation. Diagnostic functions include setting and ensuring the maintenance of diagnostic standards. National reference laboratories also coordinate laboratory services within Member States and recommend testing repertoires, laboratory techniques and equipment. The national reference laboratory should ensure adherence to the agreed standards by ascertaining that diagnostic tools (equipment) are appropriate, that the reagents which are introduced into the Member States are suitable for the intended diagnostic purposes, and that personnel are trained adequately to perform in the required areas. The national reference laboratory should also coordinate an effective referral system of specimens within and outside the Member States. In order to fulfil this function, the national reference laboratory should coordinate laboratory information management.

Public health functions are the preserve of national reference laboratories and are not ordinarily performed by other laboratories in the Member State network. They include participation in policy formulation, disease surveillance and the generation of early warning indicators on possible disease outbreaks. Teams in national reference laboratories provide laboratory leadership in the coordination of epidemic preparedness and response. Other public health functions include the conduct of operational research for health and the provision of in-service training needs. They liaise with training institutions to model curricula in line with service needs. The national reference laboratories also have an advisory and mentoring role on health and safety practices within the laboratories. In addition to their diagnostic and public health functions, the national reference laboratories have overarching responsibilities for quality assurance and information management systems.

6.1 General diagnostic functions (specialised testing services)

The key diagnostic service provided by the national reference laboratories is to conduct tests that are not performed elsewhere in the national network of laboratories. These include complicated tests requiring high levels of technical expertise and the use of sophisticated equipment. In view of the combination of diagnostic, proficiency testing and training roles, the national reference laboratory test repertoire should include the entire range of tests – from the basic to the most sophisticated.

With respect to the “big three” communicable diseases, tests in this category include the capacity to diagnose HIV infection, provide disease staging and recommend the commencement of antiretroviral therapy (ART) in adults and children. The capacity to conduct more complex testing procedures (such as ribonucleic acid, RNA, and deoxyribonucleic acid, DNA, polymerase chain reaction, PCR, and viral genotyping) should be represented at this laboratory level. National TB reference laboratories should have the capacity to diagnose TB infection in any human sample using all available means.

A TB national reference laboratory should perform first-line drugs testing to determine multidrug resistance (MDR) and either perform or coordinate the performance of second-line drug sensitivity tests for the detection of extensively drug-resistant (XDR) TB with other competent laboratories. National reference laboratories for malaria should perform all malaria testing methods that are available in the Member State, in order to provide a diagnostic service, quality assurance and training.

6.1.1 Development and implementation of diagnostic policy

The national reference laboratory should play a key role in the development and implementation of diagnostic policy for laboratories in each Member State. The policies should define what tests should be performed, the broad specifications of the equipment to be used, the human and material resources required, the laboratory management and the funding of the services.

The policy should recommend the physical infrastructure, cadre and equipment required at all levels of the laboratory pyramid. This scope of the policy should holistically address service provision from health centre, through district, provincial, central, and tertiary referral levels. Implementation of the policy should be guided by strategic implementation or business plans.

6.1.2 Maintaining diagnostic standards, training and skills transfers

Within the context of the laboratory policy and strategic implementation plans, the national reference laboratory is responsible for imparting testing competence through the training of personnel both on and off site. This role requires the national reference laboratory to lead efforts of setting and ensuring the maintenance of the standards expected of a given level of diagnostic services. An extension of this role would be to contribute to the syllabi of training institutions. The national reference laboratory is also responsible for the evaluation of novel diagnostics, equipment, reagents and consumables. This ensures that diagnostic equipment introduced into Member States is suitable and appropriate for the intended laboratory levels. To this end, the national reference laboratory works in liaison with procurement and logistics services, and tender boards to ensure that diagnostic equipment and reagents that are introduced in laboratories fulfil recommended minimum criteria. Such criteria include technical performance and reliability, ease of use, influence of extremes of temperature, availability and accessibility of servicing and maintenance logistics.

6.1.3 Servicing and maintenance of equipment

Regular servicing and maintenance ensures the operational state of laboratory equipment, but the expertise to perform this function is limited in Member States. Provisions for preventive and emergency maintenance should be available. Staff at national reference laboratories should be conversant with the service manuals for the equipment in Member State inventories. Therefore the national reference laboratories should be responsible for coordinating the servicing and maintenance of equipment within the laboratory network. The service is facilitated by a degree of equipment standardisation within the Member States. The national reference laboratories will therefore provide advisory services to procurement agencies and should be consulted by tender boards.

6.1.4 Provision of quality management systems

The national reference laboratory serves as a resource centre for quality assurance and the coordination of external quality assurance schemes for Member States. As part of quality management, the national reference laboratory is responsible for establishing and validating testing algorithms and maintaining quality standards through structured quality assurance, proficiency testing and the conduct of on-site assessments. The national reference laboratory should oversee quality management in Member States. The role requires designing quality assurance guidelines, training relevant staff members at all levels, and providing proficiency testing.

6.1.5 Information management in national reference laboratories

Member State national reference laboratories should establish and standardise information management protocols and practices. This should allow for the introduction of uniform data collection tools and for defining pre-analysis and post-analysis information management protocols. The function should be facilitated by the development and rolling out of laboratory information systems. For the purposes of epidemiological surveillance, the information gathered is most useful when linked with unique patient identifiers that make it possible to identify which (as opposed to how many) patients have a given condition.

6.2 Public health functions of national reference laboratories

Public health laboratories have a central role in the surveillance of epidemic-prone disease and other disease of public health importance. The functions are carried out through countrywide surveillance, supported by in-laboratory diagnostic capacity.

Countrywide, sometimes sentinel, surveillance requires the services of field workers, data entry personnel, epidemiologists and statisticians. The work is coordinated through logistics officers who ensure the availability of transport and other field logistics. The services carried out within the laboratories are predominantly diagnostic. The diagnostic tests are biased towards the diagnosis of specified diseases of public health relevance and those which, if left uncontrolled, could develop into epidemics. These conditions are rare outside epidemics, and require a constant state of emergency preparedness on the part of the laboratory. The public health national reference laboratory should have relevant expertise to ensure that the data obtained are of high quality. The activities should be supported by robust information management.

6.2.1 Surveillance and epidemic response

National reference laboratories support the public health functions of Member States' Ministries of Health. The services provided include the conduct of communicable disease surveillance, data collection, epidemiological analyses and dissemination. The laboratories also participate in periodic national disease surveys.Disease surveillance is an important component of health intervention and contributes to the functions of the disease control programmes. Surveillance is the mainstay of interventions in the major communicable diseases (HIV and AIDS, TB and malaria). The timely availability of accurate surveillance data across a Member State can be highly effective in mitigating outbreaks of epidemics such as the cholera and H1N1 (swine flu).

The laboratory is the operational arm of the Ministry of Health, in that it monitors the status of the target diseases through strategically positioned sentinel surveillance sites. The laboratory should devise or adapt data collection tools to enable surveillance data collection, analysis and reporting.

6.2.2 Training, qualifications and continuing professional education

The training roles of national reference laboratories are multi-layered. The laboratories advise Member State Ministries of Health on the required numbers of technical staff for each level of laboratory service delivery. This includes laboratory assistants, technologists with discipline-specific specialisation, scientists and pathologists.

National reference laboratories, in setting and maintaining the standards for testing in Member States, cannot ignore the content of training curricula offered to laboratory personnel. The laboratories recommend the required competences, and liaise with training institutions to model a cadre that will best provide the required services. Once qualified and deployed, the national reference laboratory is responsible for the conduct and coordination of in-service training and continuing professional education. The national reference laboratory is also responsible for providing training on new techniques and in the use of newly introduced instruments. This training helps maintain the standards and quality of laboratory service provision. The laboratory should therefore contribute to tailoring the syllabi of training institutions by proposing aspects that are relevant to the overall testing programmes in the country to pre-service personnel. The training role should incorporate in-service personnel through the provision of structured continuing professional education.

6.2.3 Operational research for health

The national reference laboratory, in its oversight role over the laboratory services in the country, is well positioned to identify research priorities and develop research and training programmes. The laboratory may have the capacity to address these, or it may supervise the sub-contracting of the research to other competent bodies, such as academic institutions. In this regard the laboratory should serve as an entry point and coordination service for national and international research partners.

6.2.4 Health and safety

The national reference laboratory is the ultimate custodian of laboratory excellence within Member States. This role requires adequate human resource capacity. The laboratory must be able to advise on bio-safety and to support the implementation of bio-safety measures at laboratories in the country. This involves the development or adaptation of bio-safety and infection control guidelines for use in the different laboratory services strata in Member States. This role starts with the elaboration of relevant policies, and the provision of technical advice on the bio-safety conscious design of laboratory buildings, the recommendation of suitable bio-safety equipment, advice on infection control, and the coordination of health and safety service provisions.

6.2.5 Specimen handling and transportation

The position of the national reference laboratory at the apex of the national diagnostic pyramid requires that test samples be referred for confirmatory testing. The laboratory coordinates the referral of samples to appropriate diagnostic centres within and outside the Member States. The laboratory should also coordinate the referral of samples for quality assurance.

These functions require the laboratory to have the capacity to receive and dispatch test samples. This, in turn requires compliance with the use of standardised and approved packaging, as well as coordination with couriers, port health authorities, the postal services and the airlines. The airlines are governed by the International Airline Transport Association (IATA) regulations. At Member State level, the national reference laboratory has to coordinate compliance with IATA regulations. Between Member States, there is need for a harmonisation of importation and exportation requirements for potentially infectious samples. This will ensure unhindered transport of test samples across borders.

7. MINIMUM STANDARDS FOR NATIONAL REFERENCE LABORATORIES

The national reference laboratory is at the pinnacle of the laboratory pyramid in Member States, and provides diagnostic and public health services. Its wide-ranging roles encompass testing, non-testing, administrative, advisory and supervisory roles. Other roles include guiding the standards of training of personnel to be deployed in laboratories, standardisation of equipment reagents and consumables, and the quality control of the testing procedures and results.

In order to perform these roles, the laboratory is expected to achieve and maintain certain minimum standards. Key considerations are the premises, the people working in them, policies that guide operations, the equipment and other tools of the trade, competency in the use of the equipment, mechanisms for the communication of test results and the availability of financial resources. Standards are essential for the realisation of the functions.

7.1 Policies

Member States should have written policies to guide and regulate laboratory operations. Member States must ensure that:

- There is a comprehensive policy on laboratories that addresses all relevant requirements to enable the performance of the minimum functions.
- The policies should describe the laboratory administration organogram, and recommend the physical infrastructure, human resource requirements and equipment for all levels of the laboratory pyramid, from health centres to national reference laboratories.
- The policies should address quality assurance, information management, health and safety practices, and infection control.
- The policy documents should recognise and cater for both the diagnostic and public health roles of national reference laboratories.
- The implementation of the policies should be guided by clearly defined strategic implementation or business plans.
- The plans should be buttressed by an adequate allocation of financial resources, coordinated forecasting and procurement of laboratory equipment, reagents and consumables.

7.2 Standard personnel requirements of national reference laboratories

The human resource complement of national reference laboratories is determined by the operations and size of the facility. Administrative, technical and specialised human resources should be included in the organogram. Purely diagnostic services should be provided by the best-qualified technical staff in the respective disciplines. These have been outlined for HIV and AIDS, TB and malaria. These technical members of staff have to be complemented by people with expertise in other areas, which the laboratory is assigned to perform.

7.2.1 Administration and finance

The laboratory should be run by a well-resourced administrative team, headed by a laboratory administrator or coordinator who oversees all laboratory activities and who acts as the point of liaison with Ministry of Health principals and other partners. This post should be supported by administrative assistants or secretaries.

The administration department should also oversee pre-test and post-testing logistics, including communication with any sentinel surveillance sites, and the receipt and dispatching of results. The management of stock, acquisition, storage and disbursement would be the responsibility of a dedicated logistics officer. A stores clerk may be required, depending on the extent of the operations. A dedicated team should be responsible for the financial management of the laboratory.

Specialised departments

The specialised departments are dictated by the laboratory services that are provided. They encompass the diagnostic and public health components of the national reference laboratory services. They include a contingent of specialised laboratory scientific officers with sectional oversight for departments such as bacteriology, tuberculosis, parasitology and malaria, HIV and virology.

The specialised diagnostic departments include clinical biochemists, haematologists, histopathologists, immunologists, microbiologists, parasitologist and virologists. Specialised public health departments would include a laboratory epidemiologist, biostatistician and an information technology section responsible for the management of the information hub. The responsibilities for training and quality assurance, occupational health, health and safety and infection control are overarching. Personnel can be drawn from specialised and non-specialised service departments. The surveillance services will need to be supported by appropriate field staff.

7.2.2 Proposed staffing norms for national reference laboratories

Administration

- Administrator,
- Finance officer,
- Logistics officer,
- Administrative assistants (secretaries),
- General workers (cleaners).

Specialised Services: Diagnostics

- Best-qualified specialist laboratory scientific officers and/or pathologists should provide leadership in the respective disciplines of clinical chemistry, haematology, histopathology and cytopathology, immunology, microbiology, parasitology and virology,
- Supporting scientists, technologists and technicians assigned to the departments,
- Epidemiologist,
- Biostatistician,
- Field workers,
- Animal /insect facility workers.

7.3 Human resource policy

Member States should have laboratory human resource policies. The policies should describe the human resource requirements and provide mechanisms for fulfilling those requirements. Specifically, Member States must ensure that:

- Human resource policies and the staffing norms accommodate technical (technicians, technologists, scientists, pathologists), as well as non-technical, laboratory personnel.
- Human resource policies accurately describe the qualifications expected of laboratory personnel, and recommend capacity building mechanism to ensure that candidates achieve the required qualifications.
- Staff retention policies are developed and implemented, and that these address remuneration discrepancies (thus helping reduce the brain drain).
- Facilities for basic and post-basic training of technicians or technologists are established or strengthened and that the numbers of pathologists are increased.
- Defined and structured career development pathways are charted in order to upgrade the qualifications and competencies of currently available personnel.
- Methods are developed to create synergies between national reference laboratories and academic, research or private institution staff in Member States and to leverage those complementarities.

7.4 Organisation and structure of laboratory services

The structures of national reference laboratories can differ in Member States. The typical structure is a horizontally integrated and centralised laboratory organisation. But well-resourced, vertically integrated and disease-specific laboratories have recently emerged. The view of the consensus-building workshop was that horizontally integrated laboratory organisations are preferable. Therefore Member States must work towards an integration of laboratory services.

7.5 Quality management practices

Quality management includes quality planning, quality control, quality assurance, and quality improvement. Member States should improve quality management practices by:

- Developing national quality manuals;

- Establishing quality assurance schemes, and enlisting existing accredited quality assurance schemes to assist in refining and prioritising relevant aspects of quality management;
- Appointing dedicated quality officers, and providing them with adequate resources to enable the coordination of quality assurance and proficiency testing in Member States and to oversee quality assurance officers in feeder laboratories;
- Capacitating quality assurance officers to liaise with national and external quality assurance schemes, and coordinating the referral of test samples to regional external quality assurance schemes; and
- Ensuring that the staff complement of a national reference laboratory is versatile and competent in the quality-assured performance of relevant assays. These will assist in the validation of equipment and test kits, and the recommendation of their acceptance or rejection, in line with standing recommendations.

7.6 Information management

The management of information should be integral to the provision of laboratory services. Member States should strengthen the capacity to collate accurate and complete data in order to improve disease management and allocate adequate human, material and financial resources for this purpose. Member States should therefore ensure that:

- Information management guidelines are incorporated in laboratory policies;
- The policies define the type of information to be collected, the tools and the human resources that are required, and the purpose to be served;
- Adequate budgets are allocated to provide information management logistics; and
- Electronic information management systems are established to improve data accuracy and expedite information sharing.

7.7 Laboratory physical infrastructure

The premises housing the national reference laboratory should meet certain minimum standards. It is recommended that the laboratory itself should meet the requirements of P3 level laboratories. The laboratory premises will vary in size and the structural requirements will be determined by the disciplines that are being housed. The diagnostic departments have discipline-specific requirements. Guidelines for the design and specifications of the physical structure of laboratories have been published by many authorities, including the National Institutes of Health in the USA and WHO. These vary according to the levels of biological safety and physical containment that are required. National reference laboratories will also vary according to these criteria. For national level laboratories a P3 containment level should be the target. The detailed descriptions of these requirements are available from the WHO and the CDC.

In order to meet the minimum standards for national reference laboratories, Member states must ensure that:

- The laboratory buildings are constructed from stable material and meet fire safety standards;
- The working surfaces of laboratory benches are made of appropriate materials that are impervious to water, resistant to acid, alkali, organic solvents and moderate heat;
- The laboratory buildings have adequate equipment (including fridges, freezers and cold rooms and cryo-storage facilities);
- The floor plan is designed to allow unhindered workflow;
- There is adequate natural lighting and ventilation;
- There is adequate room for patient reception, phlebotomy and ablution;
- Separate staff dining areas are provided. Depending on the services provided, controlled access should be practiced;
- Back-up electricity generators are available;
- There is adequate provision for the public health functions (including surveillance, quality management and training); and
- Adequate storage space for reagents and consumables is provided.

7.8 Servicing and maintenance of equipment in national reference laboratories

The provision of diagnostic and public health services by national reference laboratories is premised on the availability of the necessary equipment.

- Member States should therefore ensure that equipment is available in adequate quantities and quality. (Equipment items for the major communicable diseases HIV and AIDS, TB and malaria are listed in Annex II.)

- In addition to availability, Member States should ensure that there are mechanisms for servicing the equipment. The national reference laboratory should have the technical capacity to service laboratory equipment.

- The current practice of engaging biomedical engineers who are specialised in hospital equipment is no longer suitable in view of the complexity of modern laboratory equipment. Low staff complements and high workloads are associated with inordinate delays in equipment servicing. The latter can be addressed through a review of acquisition practices to incorporate service contracts.

- Additional capacity to train laboratory equipment maintenance engineers and technicians should be implemented.

- Modalities for the servicing of bio-safety cabins, microscopes and pipettes should be put in place.

- Finally, an adequate budget to cover requisite reagents and consumables is required if the equipment is to be kept operational throughout the budget cycles.

7.9 Sample transportation logistics

The national reference laboratory should have mechanisms, human resources and a budget to enable the transportation of samples within and between Member States.

- The laboratory shall develop a policy on appropriate specimen handling and transportation. It shall also liaise with transport services and ensure that the handling of bio-hazardous material originating from the Member States is in compliance with relevant regulations (including IATA rules).

7.10 Funding of laboratory services

All aspects of service delivery require funding.

- Member States should provide adequate financial resources to enable the realisation of the essential functions. The consensus-building meeting recommended that 10% of the national health budget should be allocated to laboratory services.

- However, there appears to be little appreciation and strategic analysis of the overall costs of providing quality laboratory services, and this is reflected in otherwise avoidable shortages and inadequate service provision. Various factors are at fault, including:

  - The underestimation of the costs;
  - Inadequate budget allocations;
  - Unanticipated increases in laboratory expenditure (due to unforeseen emergencies); and
  - Erosion of otherwise adequate budgets due to inflationary pressures.

- It is essential that the allocated budgets are adequate for the needs of the laboratory services.

7.11 Monitoring and evaluation

- The operationalisation of national reference laboratories will be monitored and the indicators will be in line with other SADC indicators.

- Monitoring and evaluation processes currently operational in SADC will be adapted to the regional laboratory context, as well as to centres of excellence.

- A baseline assessment of service provision will provide a basis for the evaluation of the accrual of services over defined time frames.

- Monitoring and evaluation will be augmented by capacity building in the national reference laboratories.

8. Implementation Mechanisms For the Regional Minimum Standards

The implementation mechanism defines the key stakeholders and their roles in the implementation of the standards. Furthermore, it provides guidance on how the implementation of the standards will be financed. Lastly, it identifies the critical indicators to

be monitored to ensure that the agreed standards are integrated in the work of the Member States. To this end, this section is intended to map out the path towards the domestication of the regional minimum standards, including how they will be financed and monitored.

8.1 Stakeholder roles and responsibilities

The successful implementation of the regional Minimum Standards for national reference laboratories requires the involvement of all key stakeholders at both national and regional levels. To this end, it is important to provide an outline on their roles.

8.1.1 Member States

- The SADC Health Ministers will oversee and monitor the implementation of these regional standards.
- Member States shall take a lead role in ensuring that the minimum standards are integrated to the annual work plans of their national laboratory programmes.
- Member States will assign necessary resources, particularly infrastructure, human, resources and finance. Financial support to laboratories will be in line with the *Maputo Declaration* provisions and with the SADC recommendations, which require that between 7% and 10% of national health budgets be allocated to laboratory services.
- Member States shall ensure that national laboratory programmes involve various departments in the Ministries of Health and key stakeholders in the public and private sectors (for example, donors, WHO, partners, private sector, and training institutions) to identify their roles in the implementation of the various activities articulated in the minimum standards.
- Member States shall identify challenges to implementation of each standard, identify the specific shortcomings that prevent the standards from being met, and identify the barriers and opportunities for each standard.
- Member States shall develop a detailed financial plan and avail resources for supporting the implementation of the harmonised minimum standard.

8.1.2 SADC Secretariat

The SADC Secretariat will coordinate the overall implementation and monitoring of these minimum standards on behalf of the Ministers of Health. Specific responsibilities will include:

- Advocating for implementation of regional minimum standards for national reference laboratories in relation to the commitments made by Member States (such as the *SADC Protocol on Health*, and the *Maputo Declaration*);
- Facilitating the harmonisation of national reference laboratories across Member States;
- Facilitating skills transfer and sharing of good/innovative practices, benchmarking of Member States among each other and provide a platform of sharing of good practices;
- Coordinating partners for resources mobilisation and technical support in the region;
- Facilitating the establishment of a laboratory coordination mechanism to streamline its support for laboratory services;
- Coordinating regional training programmes on laboratory services such as quality assurance and management information systems;
- Coordinate the implementation aspects of laboratory services that fall beyond the scope of individual Member States, including the modalities for trans-border transportation of test samples;
- Coordinate bulk acquisition of equipment and reagents, and facilitate their distribution; and
- Keep a register of experts and advise Member States on the availability of human resources and facilitate experience-sharing tours between Member State laboratories.

8.1.3 Other stakeholders

Other stakeholders include UN Agencies, bilateral donors and development partners. All are essential for the successful implementation of the Framework.

WHO and other UN agencies

Their roles will vary but will include:

- Providing technical support and advice to Member States on the strengthening of their national reference laboratories.
- Assisting in resource mobilisation.
- Assisting national reference laboratories in addressing their training and human resource needs.
- Making available policy documents guidelines and standards that can be used in the development of laboratory services.
- Linking Member States with new technologies and tools for diagnostics.
- Supporting resource mobilisation to assist in implementing national laboratory activities.
- Assisting Member States and the Secretariat to coordinate regional laboratory activities.

Other Development Partners

There are a number of bilateral and multilateral technical partners operating in SADC Member States. Their roles will include:

- Assisting in implementation of agreed on minimum standards.
- Advocating for strengthening national laboratory services.
- Augmenting resources to ensure implementation of the minimum standards.
- Assisting in disseminating best practices within the region.
- Providing additional human resources as needed to support implementation of minimum standards.
- Supporting the integration laboratory services.
- providing technical and financial support.

8.2 Financing mechanisms

Implementation of these minimum standards may require additional financial resource allocation by each Member State. Funding for the activities required to meet the minimum standards will be allocated within the national budget of each Member State, if these activities are not currently provided for in laboratory service budgets.
Member States shall ensure that:

- Areas that need additional financial resources are identified, with the participation of all relevant stakeholders, including UN agencies, donors, development partners, and NGOs.
- Each area that needs improvement is costed. Examples could include the costing of quality assurance, transportation and management information system.
- National laboratory `` programmes receive endorsement from their Ministries of Health where additional finances are required.

8.3 Monitoring implementation

8.3.1 Role of Monitoring and Evaluation in Implementation of Minimum Standards

These minimum standards need to be monitored in order to enable both Member States and the SADC region to objectively assess whether Supranational Reference Laboratories (SNRLs) are devolving their roles and at the same time putting in place regionally agreed on minimum standards. Monitoring is an important management tool that helps to indentify implementation progress, challenges and bottlenecks that should be addressed for enhanced impacts. Effective monitoring shows programme managers the extent to which SNRLs are making progress in institutionalising the minimum standards and addressing the challenges that may need attention. Thus, results from monitoring implementation of the minimum standards will inform decisions to fine-tune delivery of laboratory services at the regional level.

8.3.2 Monitoring and Evaluation at MS Level

Member States are the beneficiaries of services provided by SNRLs. Thus, at MS level monitoring will focus on whether MS are receiving the following from SNRLs:

- Support mentoring in:
  - Disease information managements system ;
  - Surveillance and research capacity
  - Laboratory and surveillance personnel
- Documenting “Best Practices”

- Receiving test results for specimen sent to SNRL in good time.

- Enhancement of quality assurance systems.
- Quality of services provided.

Thus, monitoring of SNRLs and Regional Centres of Excellence is in terms feedback that is provided by MS. This information will be recorded by MS when they report on the National Reference Laboratories in a separate section. This information will assist both MS and the SADC region to objectively assess whether SNRLs are moving towards realization of regionally agreed laboratory commitments and harmonisation of laboratory services across MS.

Member States will collect this information on an annual basis and prepare an annual report that is part of their report on National Reference Laboratories. The detailed variables on which information will be collected are in a separate document "Framework for monitoring progress in implementation of regional Policies and Frameworks".

8.3.3 Monitoring and Evaluation at the SADC Regional Level

At the SADC regional level, tracking implementation progress for the minimum standards for SNRLs will focus on issues relevant at that level. Of interest would be to objectively establish progress in institutionalising minimum standards and extent of implementation of agreed on functions. More specifically, at the regional level monitoring will focus on the following areas:

9.2 Strengthening quality assurance systems;
9.3 Strengthening diseases information management systems;
9.4 Establishment of functional referral systems for diseases specimen;
9.5 Monitoring diseases resistance;
9.6 Use of surveillance including dissemination and utilisation
9.7 Identifying priority research areas informed by surveillance data;
9.8 Development and implementation plans to enhance capacity of personnel;
9.9 Accreditation of SNRL;
9.10 Physical infrastructure;
9.11 Availability of requisite equipment;
9.12 Systems of storing and transporting specimen

Specific details on the information to be collected are contained in the "Framework to monitoring implementation of regional Policies and Frameworks" document. This information will be reported by SNRLs every year latest by 30 April to the SADC Secretariat and will assist the region to make informed decisions in terms of mobilizing resources to support strengthening the functioning of SNRLs.

8.3.4 Reporting Mechanisms

Member States will prepare national laboratory reports that include information on SNRLs every year. The reports will be submitted to the SADC Secretariat annually by 30 April. The reports that will be submitted by MS will also describe challenges that MS are experiencing in devolving their functions and implementing Minimum Standards for SNRLs. On the basis MS reports, the SADC Secretariat will compile an annual regional laboratory report that shows progress in the implementation of Minimum Standards for both National Reference Laboratories and SNRLs in the SADC region. The laboratory report will be part of the diseases annual reports (HIV and AIDS, TB and Malaria). Thus, the submission of MS laboratory reports will be in line with submission of national diseases annual reports as detailed in the "SADC Harmonised Surveillance Framework for HIV and AIDS, TB and Malaria".

The SADC Secretariat will share the report with HIV and AIDS, TB and Malaria managers and Laboratory Experts from SADC MS and partner organisations for their review and comments by end of June annually. MS will share their comments with the SADC Secretariat by mid-July every year after which the report is presented to senior officials from MS Ministries of Health and Ministries responsible for HIV and AIDS for review and recommendation to Ministers of Health and Ministers responsible for HIV and AIDS. The report will then be presented at a joint meeting of Ministers of Health and Ministers responsible for HIV and AIDS that is held once a year further review and approval.

The component of the laboratory report will be analysed to identify implementation challenges and recommend concrete solutions to the identified bottlenecks. Thus, the component of the SNRL will be used for decision making and policy reviews at both the national and regional levels.

ANNEX I: Specific national reference laboratory functions for the major communicable diseases

HIV and AIDS

A national reference laboratory must retain the technical capacity to diagnose HIV infection, provide disease staging and recommend the commencement of antiretroviral therapy (ART) in adults and children.

The laboratory should have the capacity to utilise all methodologies that are available in the Member State. Simpler methods (such as immunochromatographic tests) are reserved for hands-on training of personnel. The more complex methods (such as polymerase chain reaction and genotyping) would generally be used for the diagnoses of tests that are referred to a specialised facility.

Diagnostic capabilities of an HIV national reference laboratory

Competence in the following HIV diagnosis methods should be present:

- Rapid tests for the purposes of training and quality assurance;
- Enzyme immunoassays (ELISA);
- Confirmatory tests, including the Western blot;
- Capacity to confirm equivocal diagnoses;
- The ultrasensitive p24 antigen testing (depending on testing algorithms);
- Viral load determination using reverse transcriptase polymerase chain reaction (RT-PCR); and
- Dry blood spot analysis for infant diagnostics.

There needs to be a capacity to establish criteria for treatment initiation in adults and children through:

- CD4+ T lymphocyte absolute counts;
- CD4 percentages (important in paediatric populations); and
- Quantisation HIV RNA by polymerase chain reaction.

Also required is the capacity to monitor patients during ART through:

- Haematology analyses;
- Clinical Chemistry analyses;
- Monitoring plasma viral loads using polymerase chain reaction;
- The detection of HIV drug resistance.

Equipment requirements

An abridged listing of specific pieces of equipment to fulfil the diagnostic, staging and treatment monitoring functions of an HIV national reference laboratory is listed in Table A1.

Table A1: List of equipment required for an HIV reference laboratory

Human resource requirements for HIV diagnosis

In addition to administrative and support staff that operate in the national reference laboratory, the HIV diagnosis and treatment monitoring service requires specialised laboratory scientists/technologists. Areas of specialisation relevant to the HIV laboratory include immunology, haematology, serology, clinical chemistry and molecular biology. Senior supervisory personnel (including pathologists) may be required.

Tuberculosis

A national TB reference laboratory should have the capacity to diagnose TB infection in any human sample, using all available means. The diagnosis is followed by the culture, using the solid Lowenstein-Jensen (L-J) media slopes and the liquid (MIGIT) system. A national TB reference laboratory should have the capacity to employ either or both methods.

The determination of drug susceptibility is of paramount importance in view of the emergence of MDR- and XDR-TB. A TB national reference laboratory should have this capacity, at least for first-line drugs. It is desirable for laboratory to be able to differentiate between pathogenic and non-pathogenic TB, and it should have the mandate to provide those test results to the Member State or to provide the logistics so that they can be performed elsewhere.

In view of the combination of diagnostic, proficiency testing and training roles, the TB national reference laboratory test repertoire should include the whole range of tests – from basic to the most sophisticated tests available in the Member State. Finally, the laboratory should be able to perform line-probe assays, which are currently being introduced.

Diagnostic functions

The diagnostic functions include:

- Microscopic diagnosis of tuberculosis;
- Facilities for TB culture using either or both solid and liquid media;
- The capacity to differentiate between pathogenic and non-pathogenic mycobacteria;
- The capacity to conduct drug sensitivity testing using standard first-line panels;
- The capacity to conduct second-line drug sensitivity testing;
- Provision of the laboratory with the capacity to confirm all new diagnoses of MDR- and XDR-TB; and
- The capacity to perform line probe assays.

Essential equipment

Bio-safety cabinet (BSC class II)
ELISA micro plate washer and reader
Western blotting apparatus
Flow cytometer for immunophenotyping with reagents and consumables
Polymerase chain reaction set up for both DNA and RNA testing with accessories (Thermal cycler Reader, washer, extractor),micro centrifuge, centrifuge
Equipment for elution of Dried Blood Spot
Basic clinical chemistry analyser
Haematology analyser
Lactate analyser
DNA sequencing equipment for HIV drug resistance testing

The equipment required for the diagnosis of TB is listed in Table A2.

Table A2: List of equipment required for a tuberculosis diagnostic laboratory

Autoclaves
Biological safety cabinets (BSC Class II with germicidal UV lighting)
Light microscopes
Fluorescent microscopes
LED microscopes
Staining and slide-drying equipment
Reagents and consumables, including stains
Centrifuges
MIGIT liquid culture systems (MGIT manual or MIGT 960)
-80oC freezer
-20oC freezer
Refrigerators 2°C to 8°C
Incubators
Inspissators
PCR gene probe assay
Weighting scales
pH meters or pH indicator strips
Water baths liquid nitrogen
Ovens
Plate counter
Water bath
Centrifuge
Sonicator
PCR lab complex and equipment (amplifier, thermal cycler)
Gel electrophoresis equipment
Negative pressure laboratory facilities for TB culture and drug sensitivity testing
ELISA reader
Micro centrifuge
Vortex
Disinfectant
Paper towels
Wash-up

Human resources

In addition to technical personnel, the TB national reference laboratory should be served by administrative, surveillance, information technology, logistics and other support staff. Core members of the technical staff should include:

- Microbiologist;
- Molecular biologist;
- Laboratory scientists (microbiology);
- Laboratory technologists;
- Instrument technician; and
- Laboratory assistants.

The numbers will vary with the workload, and additional responsibilities for quality systems management, health and safety and infection control can be assigned to these members.

Malaria

The national reference laboratory for malaria diagnosis should have the capacity to perform all malaria testing methods that are available in the Member State, in order to fulfil the dual responsibilities of providing a diagnostic service, quality assurance and training. In addition to the basic tests, the laboratory should have the capacity to detect drug resistant mutations of the malaria parasite by molecular tests including polymerase chain reaction.

Malaria diagnosis

The basis of malaria diagnosis is the examination of an appropriately stained blood film on a slide. Differences between the species can be identified. Additional tests include a range of rapid diagnostic tests, many of which are still being evaluated in some member states. The use of molecular techniques (including polymerase chain reaction) is being piloted in the investigation of parasite resistance to current drugs. It is hoped that once validated, these will speed up the diagnosis of parasite drug resistance and enable changes in policy to be introduced. The tests would include:

- Microscopy;
- Rapid diagnostic tests; and
- Molecular methods (including polymerase chain reaction).

Equipment

The range and sophistication of equipment used for malaria diagnosis is limited. In addition to general laboratory equipment, the malaria laboratory utilises light microscopes and accessories for the staining and drying of slides, as well as hand tally counters.

Human resources

The personnel required for a malaria national reference diagnostic service include:

- Parasitologist or microbiologist;
- Molecular biologist;
- Laboratory scientists (microbiology);
- Laboratory technologists;
- Instrument technician; and
- Laboratory assistants.

ANNEX II: Infrastructure and equipment requirements for a national reference laboratory

Physical plant

Some equipment requirements are discipline-neutral. In the SADC context, the availability of back-up electricity generators and adequate water storage, for example, is essential. Buildings should be equipped with sinks for hand washing, autoclaves, deionisation/water purification facilities, a glassware washing facility, an oven for baking glassware, crushed ice machine and ice buckets and fume hoods. The range of refrigeration facilities should include refrigerators, -20oC , -70oC or -80oC freezers, and liquid nitrogen storage facilities.

Equipment

If cell culture work is envisaged, laminar flow hood, biological safety cabinet (Level II), CO2 incubators, microscopes including inverted microscopes, high- and low-speed centrifuges, ultracentrifuge and a dark room may be considered.

Other equipment depends on the specifications of the laboratory, but should include electrophoresis equipment, water baths, vacuum oven, vacuum pumps, lyophiliser, spin vac, spectrophotometer, sonicator, pH meter and calculators. There will be need for access to personal computers and relevant software packages.

Small equipment and the reliable supply of consumables are crucial for the performance of analyses and are essential for the functioning of the laboratory. This includes mechanical pupating: Pipetman, Gilson or Eppendorf 0-20, 0-200, -0-1000ul, with appropriate tips. Autoclaving requires leak-proof autoclave bags. Personal protective clothing includes laboratory coats, NP95, masks and gloves.

Immunophenotyping in an HIV and AIDS laboratory requires a flow cytometer and single, dual, three-colour, or four-colour reagents and consumables (such as erythrocyte lysing, fixation and permeabilisation solutions and calibration standards). The major producers of flow cytometry reagents are BD, COULTER and DAKO.

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