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Distribution: General

Guidelines on Quality of Diagnostic Reagents for Health Laboratories

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Foreword

HEALTH laboratories are expected to generate reliable results in order to support prevention, control and management of diseases both in clinical and public health settings. Various factors influence the quality of the results. These include trained manpower and standard methodology, appropriate equipment and availability of quality reagents and kits. The quality of diagnostic reagents and kits in particular has assumed critical importance because of variations in quality. The emergence of HIV/AIDS and infections such as hepatitis B, C and E, whose diagnosis depends entirely on laboratory tests, has resulted in the availability of a variety of diagnostic kits in the developing countries, which have weak regulatory mechanisms to ensure their quality. These diagnostic reagents/kits also consume considerable amounts of scarce resources that are available to health laboratories in developing countries. It is, hence, important to ensure the quality of these reagents/kits produced locally as well as imported through different mechanisms. Lack of specific guidelines has slowed down the efforts of the Member Countries in ensuring the quality of these vital inputs for efficient working of health laboratories and thus compromising the release of reliable results. WHO has brought out these guidelines on quality of kits produced locally or those that are imported which encompass legal, technical and administrative aspects and provide a strong base for ensuring the quality of diagnostic reagents and kits.

I am sure these guidelines will be of great use and relevance to Member Countries in the selection and procurement of quality diagnostic kits and reagents.

Dr Uton Muchtar Rafei
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Preface

A vast majority of communicable diseases are prevalent in the developing countries. Various emerging and re-emerging infections have also assumed great public health importance. The use of quality reagents and kits can ensure accurate diagnosis for the management of these diseases. Advances in modern technology have facilitated production of innumerable diagnostic kits and reagents for infectious diseases. In the absence of any policy guidelines and adequate infrastructure, the health laboratories may be offered sub-standard diagnostic kits thus adversely affecting the quality and reliability of the investigation.

Most of the developing countries do not have technical support or sufficient resources to develop their own infrastructure that will assure the quality of both imported as well as indigenously produced diagnostic reagents and kits. It was thus considered imperative to develop policy guidelines on quality testing, licensing and procurement of diagnostic kits and reagents adaptable by Member Countries. This would strengthen the health infrastructure leading to proper selection of quality diagnostic kits, utilization of which will result in accurate diagnosis and better quality of care. To achieve this objective an intercountry workshop was organized in Jakarta, Indonesia during May 2001 to review the situation, identify constraints and develop policy guidelines regarding diagnostic reagents/kits. We earnestly hope that these guidelines formulated after this workshop shall be of use to national policy-makers as well as technical personnel in initiating measures that will assure the quality of various diagnostic kits and *in vitro* diagnostic devices.

Acknowledgments

THE draft on Policy Guidelines for Quality Assurance of *in vitro* Diagnostic Devices was finalized at a meeting on Quality Assurance of Diagnostic Reagents in Health Laboratories organized in Jakarta, Indonesia from 8 to 11 May 2001.

The valuable contributions of all the experts listed in the Annex are gratefully acknowledged.

1. INTRODUCTION

Diagnostic kits or *in-vitro* diagnostic devices (IVDs) are being increasingly used to identify communicable diseases including transfusion transmissible infections. These devices may be sold and used indiscriminately where systems of regulations do not exist or are inadequate. The results are transmission of infection through blood transfusion, inaccurate diagnoses and poor epidemiological information. The international movement of IVDs between countries may remain unchecked and often uncontrolled. Importing countries with functioning national regulatory systems can evaluate these devices to assure they meet international standards. Those countries which do not have adequate infrastructure to evaluate and assure the quality of IVDs require a comprehensive national policy and strong regulatory mechanism. This will support safe blood, accurate diagnoses and reliable epidemiological statistics.

A national policy is an essential component of the strategy to ensure that only quality IVDs are made available to the users. The regulatory mechanism can be implemented through the National Regulatory Authority (NRA) which is the agency in which all the legal powers for assuring quality of IVDs are vested.

The National Reference (or Regulatory) Laboratory (NRL) should provide the advisory technical support for the NRA. It should operate a comprehensive system for assuring the quality of IVDs prior to marketing and in post-market surveillance. Its operation must be independent from the NRA.

In all the countries of the South-East Asia Region (SEAR) of WHO a national regulatory authority for assuring quality of pharmaceutical products is functional. The indigenous production and import of various pharmaceutical products should be regulated by this agency with appropriate legislative support and legal framework. This legal framework could be used for the establishment of policy guidelines for quality assurance of IVDs.

These guidelines may be used to structure a regulatory system and its implementation to minimize the transmission of transfusion-transmissible infections, to assure accurate diagnosis in communicable diseases and to enable the production of accurate epidemiological information.

Aim

To provide guidelines for the development of a national infrastructure which will support and maintain the quality of *in vitro* diagnostics (IVDs) for the use of blood transfusion services, surveillance, and diagnostic laboratories.

Objectives

- To define the elements of the infrastructure required to support the quality of IVDs in screening and diagnosis programme;
- To show the relationships between organizational groups involved in regulating the quality of IVDs;
- To define the functions of each of the organizational groups;
- To offer an implementation plan for each organizational group, and
- To provide detailed information in some areas to support the institution of the overall system.

2. KEY ELEMENTS

A national policy on assuring the quality of diagnostic kits is an essential component of the strategy to ensure that only quality diagnostic IVDs are made available to the users, leading to quality care in both clinical and public health settings.

A national policy to assure quality of diagnostic kits should define the strategy for implementing measures that culminate in availability of quality IVDs. This should include the following key elements.

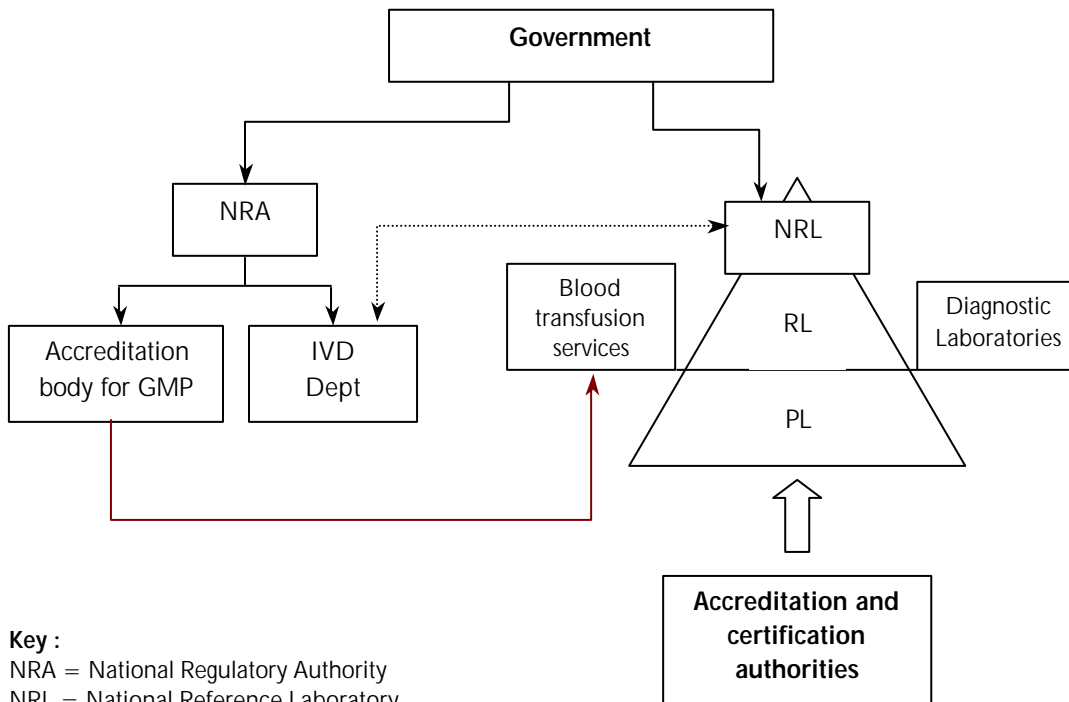
- A commitment by the government that quality IVDs are essential prerequisites of assuring the quality of clinical care and public health through the formulation of appropriate laws, development of policy and allocation of resources;
- A National Regulatory Authority (NRA) that has sufficient infrastructure and capability to define and implement measures to assure quality;
- Establishment or identification of one or more independent National Reference Laboratory (NRL), with the infrastructure, expertise and

resources to evaluate specific diagnostic kits that are imported or indigenously produced;

- Networking and communication within the country and internationally, and
- Information exchange facilities between NRA, NRL, international bodies and referral centres.

3. ORGANIZATIONAL SET-UP

Various organizations are involved in implementing an efficient regulatory mechanism. The possible interrelationship between these is suggested in Fig below.



Key :

- NRA = National Regulatory Authority
- NRL = National Reference Laboratory
- IVD Dept = *In vitro* Diagnostics Department of NRA
- RL = Reference Laboratories
- PL = Provincial Laboratories

4. IMPLEMENTATION OF GUIDELINES

4.1 Law and Policy

- If the law does not exist, a national policy is to be framed by an expert group whose recommendations shall be based on current international practices.
- If the existing law does not include *in vitro* diagnostics, it should be amended to include these under medical devices.
- National committee(s) to be assigned the task of drafting policy guidelines; (See Annex 1: constitution of national committee(s)).
- National committee formation to be initiated by NRA or relevant department of government.

4.2 National Regulatory Authority

- A division of NRA must be identified to be responsible for affairs relating to IVDs.
- Working infrastructure should be created within and with other national/international bodies.
- Quality management system as per international guidelines should be established.
- Mechanism for information exchange should be instituted.
- Capacity should be built by training and resources.

4.3 National Reference Laboratory

- Identify NRL(s) – There may be more than one reference laboratory for each area (see Annexes 3 and 4)
- The working infrastructure of NRL should be established.
- Quality management system should be based on international guidelines.
- Mechanism for information exchange should be created.
- Facilities, resources and training should be ensured.

4.4 Networking

- National/regional
- International

5 ROLE OF VARIOUS ORGANIZATIONAL GROUPS

5.1 The Government

- Appropriate legislation should be enacted.
- National committee(s) should be set up for development of policy.
- NRA /IVD department with the designated premises, personnel, financial and technical resources should be set up.
- The NRL should be identified and authorized for evaluation

5.2 National Regulatory Authority

- The national policy and guidelines on assuring the quality of diagnostic kits should be implemented.
- Standards for assuring the quality, safety, efficacy and timely availability of IVDs should be developed.
- An administrative framework should be devised for implementation of the policy.
- Good manufacturing practices (GMP) should be in use in the premises of the manufacturers.
- Licenses for import of indigenous IVDs should be issued and a register of licensed IVDs maintained.
- A system to evaluate and monitor the IVDs should be established after these have been released into the market (Post Marketing Surveillance).
- Incident-reporting and recall mechanism should be developed and implemented should there be deviations in the quality of the kits after their release.
- Research and development must be facilitated.

- The legal, technical and environmental aspects of the diagnostic kits should be periodically reviewed for appropriate amendments.
- Training courses for industry and regulatory personnel on topics relating to regulatory matters should be organized.

5.3 National Regulatory Laboratory

- The technical capacity to implement the examination of IVD devices submitted for NRA approval should be developed. The examination should be based on international standards. The laboratory will make recommendations concerning the suitability of the device for registration.
- Consistency of quality in the use of IVDs should be established through the general instruments of total quality management.
- Training courses should be organized and training material developed on all aspects of quality management for all laboratories.
- International reference material should be provided.
- Reference testing should be conducted.
- Relevant research and development should be conducted.
- National databases relevant to quality assurance must be managed.
- Linkages must be developed with national and international laboratories to assure exchange of information.

5.4 Regional and District Laboratories

- Quality management should be ensured in their working.
- They should participate in quality assurance programme
- The required data should be returned to NRL.
- Only certified IVDs must be used.
- Networking with other laboratories for information exchange should be encouraged.

Annex 1

COMPOSITION OF NATIONAL COMMITTEES

The suggested composition of the national committee which would advise the national government, national regulatory authority and the national regulatory or control laboratory could be as follows:

- (1) Director-General of Health Services, Ministry of Health (Chairperson);
- (2) Head of National Regulatory Authority (Convenor);
- (3) Director of the Medical Research Council of the country;
- (4) WHO Representative;
- (5) One legal expert;
- (6) Director of the National Reference Laboratory;
- (7) Director of the National Vaccine & Biologicals production institute;
- (8) One microbiologist of national repute, and
- (9) One expert in the area of diagnostic kit development and testing.

Annex 2

GOOD MANUFACTURING PRACTICES

Good manufacturing practices for the production of IVDs should be in line with those suggested for production of other biological and pharmaceutical products. These have been described in various WHO publications and Reports of the Expert Groups (Technical Report Series).

- (1) The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or safety of the patients, and the safety or health of users.
- (2) The devices must be designed and manufactured in such a way that they are suitable for the purposes as specified by the manufacturer, taking account of the generally acknowledged latest technology. They must achieve the performances, in particular, where appropriate, in terms of analytical and diagnostic sensitivity, analytical and diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer.
- (3) The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons.
- (4) Where a device incorporates biological substances, the risks of infection must be reduced as far as possible by selecting appropriate donors and appropriate substances and by using appropriate, validated inactivation, conservation, test and control procedures.
- (5) Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.
- (6) Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial

contamination; the packaging system must be suitable, taking account of the method of sterilization indicated by the manufacturer.

- (7) Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users.

If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.

Annex 3

REQUIREMENTS FROM MANUFACTURERS FOR EVALUATION OF IN-VITRO DIAGNOSTICS

- (1) The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the devices concerned, as specified in the law.
- (2) The declaration of conformity is the procedure whereby the manufacturer ensures and declares that the devices concerned meet the requirements.

Quality system

- (1) The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- the name and address of the manufacturer and any additional manufacturing site covered by the quality system,
- adequate information on the device or device category covered by the procedure,
- a written declaration that no such application has been lodged with any other notified body for the same device-related quality system,
- the documentation on the quality system,
- an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,
- an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,
- an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action and notification.

- (2) Application of the quality system must ensure that the devices conform to the provisions at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

- (a) the manufacturer's quality objectives;
- (b) the organization of the business and in particular:
 - the organizational structures, the responsibilities of the managerial staff and their organizational authority, where quality of design and manufacture of the devices is concerned,
 - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and product, including control of devices which fail to conform;
- (c) the procedures for monitoring and verifying the design of the devices and in particular:
 - a general description of the device, including any variants planned,
 - all documentation , and
 - the techniques used to control and verify the design and the processes and systematic measures which will be used when the devices are being designed;
- (d) the inspection and quality assurance techniques at the manufacturing stage and in particular:
 - the processes and procedures which will be used, particularly as regards sterilization,
 - the procedures in relation to purchasing,
 - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

- (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration.

The manufacturer shall carry out the required controls and tests according to the latest technology. The controls and tests shall cover the manufacturing process including the characterisation of the raw material and the individual devices or each batch of devices manufactured.

- (3) The notified body must audit the quality system to determine whether it meets the requirements. It must presume that quality systems which implement the relevant harmonized standards conform to the requirements.

The assessment team must have experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision shall be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

- (4) The manufacturer must inform the notified body which approved the quality system of any plan, for substantial changes to the quality system or the product-range covered.

General Requirements for ELISA-based Kits for Detection of HBs Ag, Antibodies to HIV and HCV.

Sl. No	Specifications	HBs Ag	Anti HIV	Anti HCV
1.	Purpose	Detection of hepatitis B surface Antigen.	Qualitative detection of antibodies to HIV1 & HIV 2.	Qualitative detection of antibodies to HCV
2.	Coating reagent	Recombinant or monoclonal antibodies	Recombinant or synthetic antigens	Recombinant or synthetic antigen

Sl. No	Specifications	HBs Ag	Anti HIV	Anti HCV
3.	Kit requirements	Five Kits each from three consecutive batches with a minimum of 500 tests.	Five kits each from three consecutive batches with a minimum of 500 tests.	Five kits each from three consecutive batches with a minimum of 500 tests.
4.	<p>Documentation requirement</p> <p>1. Imported</p> <p>Along with the kits, the manufacturer / importer must provide a complete dossier having the following information:</p> <p>Letter from Drugs Controller General / or State Drug Controller / directing national control laboratory to evaluate the kit ; Quality Control (QC) protocols / certificate of analysis for the lot submitted for evaluation describing QC of each component of the kit in detail as carried out by manufacturer. The documents should be original and signed by the QC department of the manufacturer along with the seal of the manufacturer; Evaluation reports or clinical data for the kit, if any; Studies undertaken to correlate data with field results ; Stability Data ; Name of the countries where the kit is already in use; In case of imported product, National Control Authority certificate from the country of origin / batch release certificate / certificate of export of the product. These should be in English language. If a foreign language is used, translation of the certificate by an authorized official may be submitted; Any change in the manufacturing process / Raw material source ; Kit insert - original in English language (In case of other languages, authenticated translated English version should be submitted). The name of manufacturer along with the address should be printed in kit insert.</p> <p>All documents should be legible, signed, dated and fixed with seal.</p> <p>2. Indigenous</p> <p>Detailed in house QC testing documents ; Evaluation of reports / clinical trials of the product ; Details of manufacturing procedure (SOPs) with quality control of raw materials and final product ; Details of annual production ; MOU for purchase of raw material.</p>			

Sl. No	Specifications	HBs Ag	Anti HIV	Anti HCV
5.	<p>Kit package</p> <p>1. Kit package should include:</p> <p>Name of product; Name and address of manufacturer; Name and address of importer / supplier, import license no.; Lot no. and expiry date of the kit; recommended temperatures of storage; A statement showing that components may or may not be used with other lots of the same kit may be provided; Components of the kits with lot no., expiry date; Purpose for which kit is intended.</p> <p>2. Containers should include:</p> <p>Name of product; Name of manufacturer; Lot no, and expiry date; Storage temperature; Volume; Caution drawing attention to hazards (e.g. For lab use and <i>in vitro</i> use)</p> <p>3. Kit insert requirements</p> <p>The following information must accompany the kits:</p> <p>Type of assay; Principle of the test along with details of antigens used, their source and quality control; Kit storage - conditions e.g. temperature recommended; No. of strips / kit; Suitability of the test; List of reagents; Any other reagent / material required but not supplied in the kit; Any special conditions / equipment (make and model no.) required for performing the test; Safety considerations and hazards associated with the test; Specimens that can be tested along with the data for each kind of material used and dilution to be used for each specimen; For controls, if dilutions are required, they should be clearly stated along with the methodology to be; Volume of sample required for testing and final dilution in the test; Details regarding conjugate and substrate; their preparation and storage conditions; Time required for performing the test; Optional procedures for performance of tests; Calibration procedure, validity criteria calculation and reporting criteria; Performance characteristics of the kits; Limitations of the kit including information on cross reactivity; Inter and Intra assay variability data; Flowchart for test procedure; Waste disposal.</p>			
6.	<p>Criteria for kit assessment</p> <p>1. Physical Inspection</p> <p>Adequacy of number of tests per lot received; Cold chain condition to be assessed; Seal on the kit to be checked; Label on containers; product name; manufacturer's name; components of the kit; Lot no; Batch no.; Storage conditions as mentioned on the kit box; Expiry date; Purpose of the assay.</p>			

Sl. No	Specifications	HBs Ag	Anti HIV	Anti HCV
	<p>2. Performance</p> <p>Contents of the different components in kit whether sufficient or not; Details of material supplied and not supplied in a kit; Suitability for samples like serum / plasma/ CSF / whole blood / any other; Kit insert; validity criteria; Determination of sensitivity and specificity against reference panel; Suitability of the kits for diagnostic / blood banking for any other purpose as per the standards.</p> <p>6.3. Criteria for acceptance (to be developed by NRA)</p>			

Quality Requirements for Rapid Kits for HIV, HBV and HCV

General Requirements for Rapid Kits for Detection of HBs Ag, Antibodies to HIV and HCV.

In Rapid Kits requirements are similar to that of the ELISA Kits except for the specification listed below.

Sl. No	Specifications	HBs Ag	Anti HIV	Anti HCV
1.	Nature of Sample	Serum, Plasma and Whole blood.	Serum, Plasma and Whole blood.	Serum, Plasma and Whole blood.
2.	Principle of the test	Latex agglutination and Immuno Chromatography	Latex agglutination and Immuno Chromatography	Latex agglutination and Immuno Chromatography
3.	Criteria for acceptance (to be developed by NRA)			

Annex 4

FUNCTIONS OF NATIONAL REFERENCE / REGULATORY LABORATORY (NRL)

- (1) Evaluation of designated IVDs;
- (2) Support to NRA's regulatory responsibilities and liaison with Department of Health;
- (3) Adjudication of difficult serodiagnosis and reference testing;
- (4) Development and maintenance of panels;
- (5) Conducting NEQAS;
- (6) Establishment of academic affiliations;
- (7) Conducting/assisting in accreditation of laboratories;
- (8) Maintenance of national database for QA materials and documentation activities;
- (9) Acting as a nodal centre for national and International networking in the area of IVDs;
- (10) Conducting market surveillance and adverse incident reporting;
- (11) Conducting relevant research;
- (12) Providing training courses / workshops for laboratory staff and programme planners;
- (13) Certification of GMP for indigenous manufacturers of IVDs, and
- (14) Recommending quality tested IVD products for licensing by NRA.

Annex 5

FUNCTIONS OF REGIONAL AND OTHER LABORATORIES

- (1) Participation in NEQAS;
- (2) Use and advice of only approved IVDs;
- (3) Providing periodic feedback to NRL on the ongoing QA system in the respective region;
- (4) Participation in post-marketing surveillance studies;
- (5) Network with NRL and other laboratories on information dissemination and on confirmation of difficult serologic assays and for respective testing, and
- (6) Getting accredited by the NRL.

Annex 6

INFORMATION TECHNOLOGY: ROLE AND REQUIREMENTS

Role:

- (1) International electronic networking between NRAs and NRLs of developed and developing countries including SEAR;
- (2) Intranational electronic networking between NRA, NRL(s) and regional laboratories;
- (3) Efficient conduct of NEQAS and IEQAS, and
- (4) Documentation and information exchange.

Requirements:

- (1) Computer, accessories and Internet facilities;
- (2) Computer literacy of all staff of NRA, NRL(s) and other laboratories;
- (3) Ready availability of international software packages, and
- (4) Development of application oriented softwares appropriate to Member Countries and participating institution / laboratory.

Annex 7

METHODS OF QUALITY ASSURANCE PROGRAMME, INCLUDING EQAS

The general guidelines of Quality assurance are as outlined in Annex 2.

The salient aspects of EQAS is outlined below:

NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME (NEQAS).

- National Control Laboratory (NCL): Identification and Establishment;
- Enrolment of all regional laboratories (RL) performing routine serological tests for HIV, HBV and HCV;
- Sensitization, training, reagent / panel sera support and networking;
- RL to identify peripheral laboratories (PL) for voluntary participation in NEQAS;
- NCL to despatch proficiency panel and quality assessment specimens to RLS;
- RLs to verify receipt of specimens in good condition without leakage/ breakage;
- RLs to perform tests provided by NCL strictly as per routine day today procedures;
- Filled in report forms and questionnaires to be returned to NCL promptly;
- NCL to decode results and inform RL for concordance and discordance;
- Congratulation for 100 % agreement;
- Identification of source of defect in discordant results including transcriptional error or non-optimal test conditions;
- Problem-solving advice / training to RL by NCL, and
- Similar procedures by RL to PLs.

Annex 8

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