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Laboratory Assessment Tool

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Global Capacities
Alert and Response

World Health Organization

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Acronyms

AST	Antimicrobial Susceptibility Testing
BSC	Biosafety Cabinet
BSL	Biosafety Level
CEN	Comité Européen de Normalisation/ European Committee for Standardization
CLSI	Clinical and Laboratory Standards Institute
CO_2	Carbon Dioxide
CSF	Cerebrospinal Fluid
DNA	Deoxyribonucleic acid
ELISA	Enzyme-linked immunosorbent assay
EQA	External Quality Assessment
EQAS	External Quality Assessment Scheme
GPS	Global Positioning System
HIV	Human Immunodeficiency Virus
HR	Human resources
IHR	International Health Regulations
IQC	Internal Quality Control
ISO	International Organization for Standardization
IT	Information Technology
IVD	*in vitro* diagnostic medical devices
LAT	Laboratory Assessment Tool
LIS	Laboratory Information System
MoH	Ministry of Health
NGO	Non-Governmental Organization
PCR	Polymerase Chain Reaction
SOP	Standard Operating Procedure(s)
TB	Tuberculosis
UN	United Nations
UPS	Uninterruptable Power Supply
UV	Ultraviolet
WHO	World Health Organization

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1. Introduction

1.1 Rationale

Laboratory services are an essential and fundamental part of all health systems. Reliable and timely laboratory tests are at the centre of the efficient treatment of patients. Moreover, prevention and management of infectious and noncommunicable diseases requires accurate laboratory diagnostic information. Many therapeutic decisions rely heavily on data from health laboratories and, at the time of disease outbreaks or other public health events, laboratories are at the very heart of the public health investigation and response mechanisms. Today's world cannot afford unreliable laboratory results, wasting precious time, precious samples, and too often, precious lives.

Laboratories offer their services to many clients: patients, physicians, or public health programmes for evidence based decisions. Many medical hospital, public health, and academic laboratories -- be they public or private -- contribute through their diagnostic activities to health care and public health improvement. In addition, animal health, food safety, and environmental health laboratories' services contribute to health care and public health security. Therefore, many public health programmes are conducting laboratory assessments for different purposes and objectives[1,2]. Some assessments focus on technical capacities of a restricted number of laboratories, such as polio or measles reference laboratories in the scope of the WHO eradication programmes. Other initiatives are aiming at assessing laboratory services widely across a country for either specific diseases (e.g. HIV or tuberculosis control programmes) or in a cross-cutting manner (e.g. laboratory assessments in the scope of the Service Availability and Readiness Assessment measurement[3], surveillance[4]).

Moreover, the International Health Regulations (IHR), adopted by the World Health Assembly in 2005, have placed specific responsibilities on WHO Member States for building and strengthening national capacities for the surveillance, detection, assessment, early notification and response to disease outbreaks and other emergencies of potential public health concern[5]. Laboratories are obviously playing a critical role in this surveillance and response process. In this framework, monitoring and evaluation of laboratory capacity require a standardized approach and methodology[6].

1.2 Purpose of document

This document offers guidance to assess laboratories and the national laboratory system. It describes a general process for assessing laboratories and provides questionnaires to help assessing the national laboratory system and individual laboratories.

The document and its questionnaires can be used as such or after an adaptation to meet local requirements or specificities and better fit the assessment context.

The intended audience of the document is any stakeholder performing laboratory assessments: national health authorities, multilateral agencies, Non-Governmental Organizations (NGOs), laboratory managers, etc.

This document does not intend to replace laboratory assessment tools that could have been developed by specific disease control programmes or initiatives such as the WHO polio laboratories accreditation checklist. It is based on the internationally recognized standards and good practices governing laboratory services but does not take into account specific national norms or regulations.

1.3 National Health Laboratory System

In this document, a health laboratory is defined as the basic unit, comprised of single or multiple rooms (technical rooms, reception, offices, storage, wash room), which operate applying scientific analytical methods to provide relevant results for a defined health-related purpose(s), such as medical research, medical diagnostics, disease surveillance, food testing, etc. A clinical or medical laboratory is a laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation[7].

Laboratory services comprise a set of activities performed by a number of laboratories whose results are used towards various purpose(s) such as clinical care, or disease surveillance. It may be assumed that in most countries one can find laboratory services organized into various administrative or geographical entities. Each entity can have a specific focus, for example: 1) a group of hospital and clinical laboratories centralized under a single administration to ensure patient care; 2) public health laboratories comprising local, provincial and national laboratories for disease surveillance and control; 3) animal health laboratories, 4) environmental health laboratories, including water safety laboratories; 5) food safety laboratories; 6) blood banking laboratories.

Individual laboratories can be part of a local, regional or international network(s) of laboratories bonded together for a stated purpose, e.g. influenza surveillance, food safety, or tiered health care delivery services. These networks can be coordinated at different levels and be organized as formal and informal (ad hoc). The same laboratory can have various purposes and participate in different networks or systems. For instance, a provincial hospital laboratory contributes of course to the patient clinical care of the hospital, but can also deliver results of public health interest, when serving as a site for routine surveillance of endemic or epidemic-prone disease (e.g. HIV, pediatric meningitis). It is also not rare to see public health laboratories combining clinical testing activities (even for out-patients) and public health activities, the first set of clinical activities serving as a source of income for the underfunded public health tests.

The role of laboratory services and the efforts to strengthen them, as crucial for both clinical and public health functions, are increasingly recognized[8,9,10]. Laboratory services are functional only if a combination of the following elements is adequate and in place:

- a well identified national laboratory leadership structure
- a functional organizational structure
- national policy
- national regulations
- appropriate testing services
- referring and networking activities (data and specimens sharing)
- infrastructures
- human resources
- reagents and equipment procurement and supplying systems
- information management

- financing system
- quality management system
- biorisk management

All these elements constitute the national laboratory system. They are interconnected and overlap each other. There are many ways to structure the national laboratory system and describe them. For instance, biorisk management can have a strong regulatory component, but can also be addressed as part of the quality management systems, or through the perspective of the level of infrastructure and human resources development. Networking activities are multiple and can cover specimen shipment, but also sample re-checking activities that are part of the quality assurance system. Therefore, although this document identified key components of the national laboratory system to be assessed, it does not pretend to describe in a perfect and ultimate way the laboratory system components.

2. Assessment preparation

2.1 Objectives of health laboratory system assessment

This document can be used to carry out assessments of the national health laboratory system and laboratory facilities. Its cross-cutting and holistic approach makes the tool appropriate for assessment and monitoring of laboratory capacities for the benefit of various stakeholders or programmes relying on these laboratory services (health care programmes, diseases surveillance and control programmes, etc...).

This generic document represents a prototype for assessment of national health laboratory system, and may require adaptation in the field. It contains guidance on carrying out an assessment with practical tools for data collection. Interestingly, it can be used either as a basis for self-assessment or for external assessment.

The assessment can:

- provide information in a standardized way on the health laboratory administrative organization and environment
- provide a snapshot of a representative sample of laboratories at various levels
- identify strengths and weaknesses of the health laboratory system
- raise awareness on the laboratories' performance at country level
- provide objective data to national decision-makers for planning and implementing laboratory capacity strengthening activities

2.2 The assessment method

To fully assess the laboratory system, two sorts of areas need to be addressed: strategic organization and support at the national level from the government (e.g. defining policies and regulatory framework), and specific technical capacities at the laboratories level. Therefore, the following assessment protocol is based on 2 complementary phases:

1. **Assessment of the structure, organization and regulations** of the national laboratory system(s) through collection of data at central level (and intermediate/peripheral level if time and resources allow and/or if health authorities are decentralized) using interviews or meetings. The assessment team can be guided by the **Laboratory Assessment Tool / System Questionnaire provided in Annex 1 and as the Excel file "Annex1_en.xls"**. This checklist is mainly intended for the health authorities in charge of diagnostic and public health laboratory management. However, this checklist could be adapted to assess other health-related laboratory systems (e.g. food safety, environmental health laboratories…).

2. **Assessment of a limited number of laboratories** that are representative of the national laboratory system and its organizational structure. The assessment team can use checklists or assessment tools provided by disease control programmes, inspection, licensing or accreditation bodies (e.g. WHO polio laboratory accreditation checklist[11]). In case such a checklist is not available or doesn't suit the laboratories to be assessed, the assessment team can use the **Laboratory Assessment Tool / Facility Questionnaire provided in Annex 2 and as the Excel file "Annex2_en.xls"**. It is recommended to assess laboratories from different entities or networks, operating under different status and funding mechanisms (public and private sector, hospital and academic sector, faith-based facilities, military facilities) and from each level of the health care delivery system (primary, secondary and tertiary, if any) and administrative organization:

    - at least 3 central level laboratories: national reference laboratories, national public health laboratories, university teaching hospital laboratories, animal health or environmental laboratories, poison center laboratories
    - at least 3 intermediate level laboratories (regional or provincial level): hospital-based, or public health laboratories
    - at least 3 peripheral laboratories (district or health center level): diagnostic laboratories (e.g., public or private laboratory)

The use of the Excel files is promoted as it facilitates data collection, allowing for automatic calculation, scoring, and aggregation of data. Alternatively, the assessment team can print the questionnaire already formatted in the annexes of this document and filled them in manually.

Combining the two questionnaires will allow the assessment team to cross-check the information given at central level by the health authorities and the functionality of the laboratory services and networks in the field. However each part of the assessment may also be used independently from the other.

2.3 Assessment planning and implementation

2.3.1 Build and prepare the assessment team

The assessment team should be built according to the Terms of Reference of the assessment mission. The assessment can be carried out by:

- staff from the Ministry of Health (and/or Agriculture, Commerce, Defense, etc.)
- WHO country office
- laboratory specialists (representatives from public health, hospital, clinical, private or academic laboratories, etc.)
- public health specialists, epidemiologists
- disease control programme officers (e.g. HIV, tuberculosis, malaria national control programmes)
- nongovernmental organizations

Roles and responsibilities of each team member should be clearly stated in the Terms of Reference. A team leader should be designated.

Training the assessors on the assessment methodology and tools is often instrumental to ensure the absence of bias in the assessment. Such training should combine theoretical lectures and field test of the assessment questionnaires. The field test also allows the refinement of the questionnaire according to the local specificities (see below).

2.3.2 Adjust the assessment protocol

The assessment team should review the Laboratory Assessment Tool / System Questionnaire (LAT/System) and the Laboratory Assessment Tool / Facility Questionnaire (LAT/Facility) and adjust them according to the local structure and needs (to do so, see below section 3.1.5 Editing the questionnaires). This can be done during or right after the training of assessors.

2.3.3 Collect documents for review

Key documents such as regulations, guidelines, and manuals should be collected as much as possible in advance. Alternatively the responding persons should be asked to prepare the documents and leave them at the disposal of the assessment team during the visit. This would allow the assessment team to save time; the team can simply confirm that these documents are effectively available and in use. A non-exhaustive list of useful documents to gather is provided below.

Key documents/information to be requested ahead of time for the LAT/System

- Terms of reference and responsible person(s) for the dedicated unit in charge of health laboratories coordination
- Official decree/text establishing the health laboratory coordination unit if applicable
- Terms of reference and composition of the laboratory advisory body if applicable
- National policy for health laboratory services (defining the goals and objectives of the national laboratory system)
- National plans to strengthen laboratory services or other plan/s including a laboratory component
- Indicators to monitor laboratory services (as part or separately of a strategic plan)
- Cost-effectiveness analysis for selecting technically and financially appropriate laboratory technologies and methods
- Documents about procurement system(s) for public laboratories
- Documents about procurement system(s) for private laboratories
- National documents describing structure of the laboratory services with lines of authority and laboratory network(s) organization
- Inventory or directory of laboratories performing clinical testing (health center, hospital, public health, academic, research, etc.) in the country
- List of reference laboratories identified for priority diseases or public health threats
- Standardized reporting forms for laboratory data
- Laboratory registration or licensing criteria
- National quality norms/set of standards
- National document identifying equipment needed at each laboratory level

- National document identifying staff (number and degree) needed at each laboratory level
- National document identifying tests performed and methods at each laboratory level
- National document describing *in vitro* diagnostic medical devices (IVD) registration procedure
- National supervision plan and supervision grid/strategy or written checklist for laboratory assessment, and examples of report of supervision
- Documents about national External Quality Assessment programme(s) including implementation of corrective actions if needed
- Example of data collected by the laboratory coordination unit (tests ordered and/or performed, logistics data, scientific data, etc.) and data collection mechanisms
- Nation-wide inventory of the laboratory workers
- Laboratory worker registration or licensing criteria and mechanism
- Laboratory worker training curricula
- Terms of reference of the dedicated unit in charge of the biosafety/biosecurity at national level
- Classification of biological risks and pathogens at national level
- National legislation on biosafety
- National policy or regulation for waste management and disposal
- National document for specimens packaging
- National regulations for the transport of infectious substances (Category A and B)
- National vaccination policy (pre-exposure prophylaxis) for the laboratory workers (Hepatitis B and other relevant diseases)

Key documents/information to be requested ahead of time for the LAT/Facility

- Average number of tests performed monthly in each discipline (clinical chemistry, haematology, parasitology, bacteriology, virology, etc.)
- Information on costs and turnaround time for test results available to patients
- Customer survey results
- Organization of the laboratory and its relationship with any other institution
- Copies of any reports on reviews (audit, etc.) by a third party available to the laboratory
- Certification, accreditation documents
- Laboratory quality manual (describing the quality system policy and the quality procedures)
- National or international guidelines in use or written operating documents: e.g. published instructions, norms, Standard Operating Procedures (SOP), bench aids, manual
- Laboratory own operating documents (instructions, SOP, bench aids)
- Laboratory instructions for the proper collection and handling of primary specimens
- Material Safety Data Sheets available for review in the immediate laboratory area
- Written instructions available for patient preparation prior to collection (e.g. glucose tolerance test)
- Standardized request form for tests prescribers

- Standardized form for results reporting
- Summary activity reports
- Logbooks or Laboratory Information System records
- Results of Internal Quality Controls and External Quality Assessment schemes
- List of manufacturers and suppliers
- Record of consumables and reagents purchase
- Inventory of consumables and reagents including consumption rate
- Equipment inventory and form(s)
- Job descriptions defining qualifications and duties
- Record of staff qualifications, training and experience
- Policy concerning the management of laboratory biorisk (biosafety and biosecurity)
- List of hazards associated with proposed laboratory work
- Biorisks categorization and control measures
- Roles and responsibilities related to biorisk management
- Emergency plans (e.g. in case of explosion, fire, flood, worker exposure, accident or illness, major spillage)
- Contingency measures planned in the event of an emergency or unforeseen event
- Instructions or guidelines for laboratory investigation of public health events
- List of the notifiable diseases the laboratory must report
- Standardized form/document to report notifiable diseases or other events

2.3.4 Plan for meetings, interviews and field visits

The assessment team should build an agenda for the assessment process. Requests for interviews, meetings and documents should be sent ahead of time to have a chance to meet the right respondents at the right time. Translations and interpretations must be planned.

For a complete laboratory services assessment, the following agenda can be used and adjusted according to the size of the country, the personnel and financial resources available, and the availability of respondents.

Day 1	Day 2 to 4	Day 3	Day 4	Day 5	Day X/X+1…	Last day -1	Last day
Meeting of the assessment team for questionnaires, methodology and agenda refinements	Training for assessors (optional)	Meeting with officials	Technical meetings or interviews with administrative stakeholders to answer the LAT/System provided as an Excel file	Mid-term review and debriefing before field assessment. Logistic arrangements	Field assessment of individual laboratories using the LAT/Facility provided as an Excel file	Debriefing of the assessment team. Exchange of information and collection of all individual assessment files	Debriefing with officials

2.3.5 Collect data

Data collection can be done using the two questionnaires provided in the attached Excel files. The assessment team's members can split into different groups covering various technical or geographical areas. Most of the persons met will have knowledge and expertise in few areas of the assessment only. Therefore the assessment team should identify the relevant questions to be asked and all respondents should not be asked all the questions.

2.3.6 Organize debriefing and cross-check the data collected

The indicators calculated during the field assessment of the laboratories (when the Excel format is used) should be aggregated. The assessors should compare answers provided by the respondents at the central or Ministry of Health level with their observation in the field (e.g. actual dissemination and use of national norms or guidelines, participation in external quality assessment schemes, supplying systems, and functionality of networks). Cross-checking of the responses from different stakeholders at the central level and field assessments of a sampling of laboratories should result in a satisfactory picture of the laboratory landscape in the country.

2.3.7 Prepare the assessment report

Ideally a draft report could be drafted during the assessment mission and shared across the team before the final day. The assessment team should agree on the report content (main recommendations) as well as the format, length and dissemination process. The assessment report can for instance follow the structure of the assessments (at administrative and laboratory levels), and include the aggregated data of the individual laboratory assessments in tables.

2.3.8 Circulate the report for clearance

The report should be circulated among the assessors before final release to the assessment initiator (health authorities, funding agency, or international organizations).

2.3.9 Disseminate the report

It is important to ensure an appropriate feedback to the persons interviewed or those assessed (e.g. health authorities, laboratory directors). It is also important to clarify with the initiator the dissemination process before the assessment takes place, particularly if the initiator is different from the national authority. Confidentiality rules should be clearly stated in the assessment Terms of Reference.

3. Questionnaire instructions

3.1 General presentation of the questionnaires

3.1.1 Description of the questionnaires

The questionnaires are provided in a PDF format that can easily be printed (as annexes to this document) but also as Excel files. The questions are exactly the same in the PDF and Excel format however the formatting is slightly different. The two Microsoft® Office Excel files run only using calculations (no macros). Absence of macros enables the questionnaires to be used on any computer, independent of the operating system language.

The LAT/System Questionnaire is available on the Excel file **"Annex1_en.xls"** and the LAT/Facility Questionnaire is available on the Excel file **"Annex2_en.xls"**. This section constitutes the user manual of the Excel files.

The files include fifteen worksheets for the LAT/System and eighteen for the LAT/Facility, entitled in English. Altering or renaming of these titles **may result in calculation error** and possibly compromise interpretation of data.

The assessment questions are gathered in modules. One worksheet corresponds to one module (Figure 1).

Figure 1: *Worksheets of the LAT/Facility*

Titles and descriptions of the modules:

- ***Cover***
  Cover page with WHO disclaimer.

- ***General Info*** (LAT/System) or ***Lab*** (LAT/Facility)
  This module must be filled in to provide general information on the assessment.

- ***Specific modules*** **(to be filled in)**
  8 specific modules detailed in section 3.2 for the LAT/System.
  11 specific modules detailed in section 3.3 for the LAT/Facility.
  The order of module worksheets in the questionnaires does not represent their level of importance/relevance.

- ***Gap analysis***
  This module allows the identification of the most significant needs and weaknesses felt by the respondents.

- ***Summary***
  A full summary of evaluation and assessment. Most of the information (e.g. indicators) is automatically filled in. The assessor can only add comments and conclusions in the text boxes at the bottom of the sheet.

- ***Language*** **(not to be filled in)**

The questionnaires can be used either in English, French, Spanish, Russian, or in other language. They are available by default in English, French, Spanish and Russian. Prior to switching languages, other fonts may need to be installed on your computer.

To switch from English to another language, do the following:

1. Select worksheet "Language".
2. Translate English version of the questionnaire (column C) in any other language in column G. The French, Spanish and Russian versions are already available in columns D, E and F respectively.
3. Toggle the cell number A3 from "1" (English) to "2" (French), "3" (Spanish), "4" (Russian) or "5" for any other language.

Any modification of the wording in the module worksheets should be done ONLY in this sheet as the cells of the other modules report to the "Language" sheet.

- ***Export* (not to be filled in)**
  This worksheet makes it possible to gather all the indicators' scores in one table that can be exported into a database, to compare the assessment results in the time for instance.
- ***Acronyms* (not to be filled in)**
  All acronyms used in the respective questionnaires are detailed here.

3.1.2 Recommendations for completing the modules

1. The assessor must first go to the language sheet to select the appropriate language in the cell A3.
2. The assessor then goes to the sheet "General Info" or "Lab" and fills in all the requested cells in column B.
3. The assessor fills in all the requested cells (columns D and E) of the specific module worksheets (8 for the LAT/System, 11 for the LAT/Facility) and the gap analysis module. A cross in column C also indicates that documents are required for completing the answer.
4. The assessor checks the indicators' calculations, fills in the text boxes "General comments on the assessment", "Conclusions and recommendations", and can insert some pictures in the appropriate box for the LAT/Facility, in the "Summary" module.

As explained in the box above, all the requested cells in columns D and E must be filled in. However, only the responses provided in the **grey cells** (column D) are taken into account to calculate the indicators. The white cells are not scored: they are proposed to answer closed questions which cannot be scored (column D), or to add information, describe a process and answer open questions (column E).

When no answer is expected in column D (in the case of an open question for instance), the corresponding cell in column D is crossed out.

A	B	C	D	E
1.	**Organization and management**			
	Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable			
		Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information
	Service hours			
1.1	*What are the days and hours of operation of routine service?*			
1.2	*If relevant, what are the days and hours of operation of emergency service?*			

Figure 2: *Example of open questions*

For most of the questions in both questionnaires, the assessor has a limited number of possible answers (generally in column D): 1.Yes; 2.Partial; 3.No; 4.Non applicable (unless otherwise advised).

Other values than those above can be entered (generally in column E) when asking:

- "Number of equipment"
- "Number of tests performed monthly"
- "Please describe"
- etc.

In any case, additional information can be given in column E or in comment boxes at the bottom of each module.

Clicking the small arrow at the right side of the cells (generally in column D) opens a box with authorized values. An error message will appear as below, when trying to enter values other than the ones listed in the drop down list:

Figure 3: *Error message in case of unauthorized value*

Hence, **THE ASSESSOR CAN ONLY ENTER AN AUTHORIZED VALUE IN THE LISTBOX**.

3.1.3 Calculations of the indicators

Calculations of module indicators are automatically performed when answering to each question.

The calculations are based on the following principles:

- answering 1 ("Yes") gives 1 point (or "100%") to the question
- answering 2 ("Partial") gives 0,5 point (or 50%) to the question
- answering 3 ("No") gives 0 point (or "0%") to the question
- answering 4 ("Non applicable") excludes the question from the calculation
- for some questions, the respondent can choose between other options such as "1.Never; 2.Sometimes; 3.Regularly" or "1.Good; 2.Medium; 3.Bad". In that case, answer gives the following scores:

1.Never	1 point = 100%
2.Sometimes	0,5 point = 50%
3.Regularly	0 point = 0%
1.Good	1 point = 100%
2.Medium	0,5 point = 50%
3.Bad	0 point = 0%

One main indicator per module is calculated from the average of all its questions. This main indicator (at the top of the worksheet) and calculations (at the right hand of the questions) are hidden by white panels that can be moved away after the sheet is unprotected (see below section 3.1.5 Editing the questionnaires). Figure 4 illustrates how calculations are displayed when the white panels are removed.

Some questions call for further detailed question(s) if the respondent chooses "Yes" (1) or "No" (3) for the first question, therefore additional questions are organized as a list. In such cases, only the average of the sub-questions or of the list is taken into account for the calculation of the module indicator. Such questions are often preceded by an indent. Figure 4 below shows an example of such questions and calculations:

4. Quality of laboratory system 65%

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

		Documents to be collected	1; 2; 3; 4	Provide here the answer to the open question/s and/or insert any additional information		
	National standardization					
4.1	Is there a national laboratory quality office for oversight of national laboratory quality programmes?	X	2		50%	50%
4.2	*If yes, name and contact details of the office/responsible person/s*					
4.3	*Please briefly describe the national quality programme/s in place*					
4.4	Are national general quality norms/sets of standards established?	X	1		100%	100%
	If yes or partial, do they address these topics:					
4.5	Laboratory organization and management?		1		100%	73%
4.6	Documentation and records?		3		0%	
4.7	Specimen collection and transport?		1		100%	
4.8	SOPs for specimen processing?		1		100%	
4.9	Personnel and education requirements?		2		50%	
4.10	Biorisk management?		2		50%	
4.11	Equipment, reagents, reference materials, consumables management?		1		100%	
4.12	Collaboration with referral laboratories?		2		50%	
4.13	Internal quality control procedures?		1		100%	
4.14	External quality assessment procedures?		2		50%	
4.15	Data and information management?		1		100%	

73% is the average of the 11 answers. This average is then taken into account to calculate the module indicator in cell C1 (here 65%)

Figure 4: *Example of calculations*

IMPORTANT NOTE:
Not answering a question excludes it automatically from the calculation, as it is the case for a "Non applicable" (4) answer. However it is recommended in as much as possible to answer all questions, as useful information can be extracted from a "Non applicable" (4) answer.

3.1.4 Analysis of the results and summary

Figure 5 shows an example of the graphic representation of indicators in the LAT/Facility with background color ranging from red to green. This allows the assessor to easily assess the conditions of each indicator:

- Red: Below 50%, requires significant improvement
- Yellow: Between 50% and 80%, some improvement is necessary
- Green: Above 80%, the laboratory is in good standing

	Average indicator	68%
1.	Organization and management	69%
2.	Documents	80%
3.	Specimen collection, handling and transport	87%
4.	Data and information management	47%
5.	Consumables and reagents	75%
6.	Equipment	30%
7.	Laboratory testing performance	70%
8.	Facilities	75%
9.	Human resources	86%
10.	Biosrisk management	64%
11.	Public health functions	70%

Figure 5: *"Summary" worksheet for the LAT/Facility*

Average indicator: This calculation is an average of indicators from all modules.

3.1.5 Editing the questionnaires

The assessor may need to modify the questionnaires to add or delete questions, add or delete indicators, or change indicator calculations.

Each worksheet in the LAT/System or LAT/Facility is protected against any modification. This is to avoid performing incorrect manipulations that may compromise calculation. Some white "panels" have been placed in certain locations to hide cells that are used for calculations, particularly on the right hand of the questions' columns.

IMPORTANT NOTE: All procedures described below refer to Microsoft® Office Excel 2003.

Figure 6: *Active sheet unprotected with Microsoft® Office Excel 2003*

Protection:

To unprotect the worksheets in the LAT/System or LAT/Facility, click on "Tools" in the menu bar in Excel to find "Protection" Then click "Unprotect sheet" as shown in Figure 6 above. This process has to be repeated for each worksheet as relevant. The reverse process can be done the same way.

Calculations:

The assessor may be able to move the white panels to reveal the calculation section to change/adapt indicator calculations.

Text:

Remember that the first step to modify the text (change, add or remove questions) should be done in the "Language" sheet (by changing the text, adding or removing a line) as the cells of the other modules report to it. Second step is to add/remove line(s) and extend/remove formula(s) generally

in columns B, D, F and G of the relevant module worksheets to add/remove question(s) and associated calculation(s).

Answer:

If the assessor would like to enter restricted values for answering new questions, he/she has to click on the answer cell (generally column D of the adequate line in the module), and click on "Data" in the menu bar in Excel to choose "Validation". It is then possible to allow different values for the cells in "Settings".

CAUTION: In editing the questionnaires, the assessor must first save his/her work in a different name so that he/she may go back to the original files.

3.2 Laboratory Assessment Tool / System Questionnaire

The Laboratory Assessment Tool / System Questionnaire (LAT/System) is available on the Excel file **"Annex1_en.xls"** and also as an annex of this document.

This evaluation questionnaire is designed to:

- describe and evaluate the essential elements of national laboratory systems (e.g. existing national heath laboratory policies, resources and activities) in a standardized way
- automatically generate numerical indicators related to the structure and organization of laboratory services in different parts called "modules"
- follow-up over time

Titles and descriptions of specific LAT/System modules:

- ***General information:*** this module gathers information concerning the country being assessed and the respondent.
- ***1. Coordination and management:*** this module reviews how the relevant ministry coordinates health laboratory services, how those are funded and procurement systems for equipment and supplies.
- ***2. Structure and organization:*** this module summarizes the general structure of the laboratory system including networking organization of laboratories and reporting mechanisms.
- ***3. Regulations:*** this module focuses on how the health laboratories are regulated (registration or licensing mechanisms, etc.).
- ***4. Quality of laboratory system:*** this module reviews the operations and quality requirements (external quality assessment, standards), as well as the supervision, certification and accreditation capacities in the country.
- ***5. Laboratory information management:*** this module examines which data are collected from laboratories, and how they are collected, analyzed and communicated.
- ***6. Infrastructure:*** this module assesses the infrastructure conditions at country level.
- ***7. Human resources:*** this module includes questions related to staff number and education in the country.
- ***8. Biorisk management:*** this module assesses the implementation of biorisk management measures at country level.

3.3 Laboratory Assessment Tool / Facility Questionnaire

3.3.1 Introduction

The Laboratory Assessment Tool / Facility Questionnaire (LAT/Facility) is available on the Excel file **"Annex2_en.xls"** and also as an annex of this document.

This evaluation questionnaire is designed to:

- assess any individual laboratory in a standardized way
- automatically generate numerical indicators related to the laboratory capacities and quality in different parts called "modules"
- follow the improvement of the same laboratory over time
- perform an evaluation based on the technical and management requirements expected according to the level of the laboratory (reference, intermediate, peripheral)

The LAT/Facility is an all-purpose generic assessment questionnaire that can be used to assess laboratories with different areas of expertise and from different levels of the health system (from basic peripheral level to specialized central level). No specific country guidelines (e.g. recommended tests and instruments) are assessed as they may vary from one country to another. It is the assessor's responsibility to compare the practices in the assessed laboratory with the national recommended practices or regulations. If such regulations do not exist, the assessor needs to compare the observed practices with the state of the art in similar settings or with the international recommendations (e.g. WHO, scientific societies, and literature).

The questionnaire can also be adapted to include some specific questions according to the purpose or scope of the assessment (refer to the section 3.1.5 Editing the questionnaires).

In addition to the LAT/Facility process, it is recommended to perform three other activities:

- take photographs to include in the "Summary" worksheet
- take GPS coordinates of the laboratory if geographical mapping is envisaged
- draw a map of the laboratory

3.3.2 Presentation of the LAT/Facility

A laboratory offers adequate services only if its results are delivered in a safe, reliable, and timely manner. Therefore, the main objectives of the questionnaire are to describe and assess objective elements that contribute to the capacity, performance, and quality of the laboratory. Quality requirements have been described widely these last years by various organizations. Some of the most popular and used documents are the ISO standard 15189:2007[7] and the CLSI GP26-A4 guidelines[12]. These documents describe the optimal technical and management requirements that ensure that the laboratory is functioning well and delivers quality results. They are very comprehensive and used widely by inspection teams or accreditation bodies to design assessment checklists. Some countries have adapted these comprehensive documents, extracting the most relevant items for their local purpose[13]. Biorisk management requirements have also been described in the CEN Workshop Agreement 15793 "Laboratory biorisk management standard"[14].

The proposed assessment questionnaire is based on the essential technical and managerial components that are required to run properly a laboratory. It does not pretend to cover all requirements described in the standards mentioned above and this questionnaire does not consist in an certification or accreditation checklist. This assessment questionnaire can be used to assess a

wide spectrum of laboratories, such as multi-disciplinary or specialized in one discipline or even one disease. It is particularly adapted to the assessment or supervision of resource-limited laboratories in countries that have not yet established very detailed laboratory regulations or standards.

Titles and descriptions of specific LAT/Facility modules:

- ***Laboratory identification:*** this module gathers information concerning the laboratory being assessed and the respondent.
- ***1. Organization and management:*** this module summarizes the general organization, financing and supervision of the laboratory.
- ***2. Documents:*** this module deals with the management of all documents handled in the laboratory: procedures, forms, reports, etc.
- ***3. Specimen collection, handling and transport:*** this module gathers information on the pre-examination procedures related to the sample collection (in or outside the laboratory), its transport to the laboratory or referral to other laboratory.
- ***4. Data and information management:*** this module examines the laboratory procedures during the post-examination phase (laboratory results management and reporting systems).
- ***5. Consumables and reagents:*** this module assesses the way consumables and reagents are managed (storage, inventory, shortage, etc.).
- ***6. Equipment:*** this module assesses and lists the laboratory equipment and its maintenance. It is possible to adapt the equipment list according to the targeted laboratories.
- ***7. Laboratory testing performance:*** this module makes it possible to manually list the relevant diagnostic tests performed in the laboratory and to assess the diagnostic capacities taking into account staff training, procedures, equipment, reagents, internal and external quality controls for each test.
- ***8. Facilities:*** this module assesses the infrastructure and work conditions.
- ***9. Human resources:*** this module includes questions related to staff management and qualifications.
- ***10. Biorisk management:*** this modules deals with the implementation of biorisk control measures.
- ***11. Public health functions:*** this module reviews how the laboratory possibly contributes to any public health programmes, such as the participation in surveillance networks, investigation of public health events (e.g. outbreaks) and/or the monitoring of trends for endemic diseases. This module is particularly adequate for public health laboratories, but also for any laboratory (academic, hospital, private, etc.) those results can be used for any public health purpose.

IMPORTANT NOTE: In the LAT/Facility module 7 (Laboratory testing performance), 200 lines are pre-set for entering relevant diagnostic tests performed in the laboratory (one test per line). Once the test type/name is entered, several questions need to be answered for each test (each line). A score per test is then automatically calculated in column T that enables a thorough analysis of performance for each test. The indicator for this module is an average of all test scores. To add line(s) to this table, the assessor should first insert line(s) at the bottom of the table, and then extend the formula of the whole last line of the table (by clicking on the excel line number and extend).

3.3.3 The assessment process

IMPORTANT NOTE: It is necessary that the assessment be carried out by a laboratory specialist or a person who has in-depth knowledge in laboratory assessment and understands the general laboratory operations.

Recommended length of the assessment:

A complete assessment of a laboratory should take at least a day for a reference laboratory and should take about 2~3 hours for a peripheral laboratory. This assessment must be carried out during opening hours, in order to be able to observe staff at work.

In addition to using the electronic or paper versions of the LAT/Facility, it is pertinent to have a notebook and a camera (ideally digital) for documentation.

Approach to the assessment and securing cooperation from the laboratory:

Before the assessment of the laboratory begins, it is recommended that the assessor explains the main purpose of the assessment. He/she may point out that this is not a control process that may lead to punitive measures.

Assessment procedures and guidelines:

The assessment should begin with a short meeting with the laboratory manager or whoever is in charge in order to describe why the assessment will be conducted, what the process will be and what the expected outcome might be. This meeting could be useful to get some information about the laboratory organization and many management items (staff, procurement of equipment, financing, etc.).

After the preliminary meeting, the assessor should visit the laboratory, following the “sample path”:

- sample or patient reception
- sampling rooms
- recording
- technical rooms (e.g. microscopy, chemistry, haematology, culture, bacteriology, serology, molecular biology)
- support rooms (e.g. glassware washing room, sterilization, restroom, guard room, stock room, repair room, secretary room, offices)

The assessor should look at the general cleanliness, the general organization, and biosafety level while manipulating samples. In each room (if applicable), the assessor may be required to perform the following tasks:

Inspect the condition and use of refrigerators

1. Are the refrigerators clean?
2. Randomly take 3 or 4 old-looking products and inspect their expiration dates.
3. Is there an internal thermometer available? If not, are there any temperature charts?

Inspect the condition and organization of incubators

1. Check the thermostat adjustments and daily temperature chart records of each incubator (ideally, it is recommended to have a thermometer inside a water can in the incubator).
2. Inspect the overall cleanliness of the incubator.
3. Inspect the maintenance of special atmospheres (e.g. 5% CO2, anaerobic, micro-aerophilic conditions).

4. Inspect blood culture bottles (if any)→ Are there any old bottles? Do all bottles have identifications?
5. Inspect the organization of Petri dishes (if any)→ Are there any old Petri dishes? Do all Petri dishes have identifications?

Inspect the condition and organization of freezers
How are the contents organized?
Apply the same considerations as for refrigerators.

Inspect the condition of microscopes (if any)
Always assess one or two slides in order to check:

1. the quality of the films and stains,
2. the condition of the microscope, and
3. the Kohler adjustment (centering of optical axes).

Check the conditions of all the other equipment
Use, maintenance, etc.

Visually evaluate the condition and cleanliness of the laboratory benches and facilities

Observe and evaluate how laboratory technologists work

1. Do they use personal protective equipment, e.g. lab coats, gloves, glasses, masks? Is Personal Protective Equipment available?
2. Are the benches clean? Do technologists disinfect their benches at the end of their work? Is regular disinfection of the laboratory benches likely?
3. Do they follow strictly the SOP (if available) or any good or recommended practice?

Examine the condition and organization of stock shelves, cards, and expiration dates of the reagents on the shelves

Inspect and evaluate how laboratory waste is managed inside the technical rooms
This is important information as it will reveal information about the laboratory's activities within the past 24 hours of the assessment.

1. Is the waste regularly emptied?
2. Are there separate waste (lid-covered?) containers for non-contaminated and contaminated wastes?
3. Is there a special solvent container (any for acids?)

Inspect the laboratory logbooks, patient records or information, and management of the results

Inspect the archives

During the visit, document the assessment by photographing the rooms, working staff, equipment, packaging delivery procedures, etc. These photographs will help illustrate and explain the conditions of the laboratory for the final report. Always request permission to take photographs.

Once the initial visual evaluation of the laboratory is completed, immediate assessment of the laboratory using LAT/Facility is recommended. The assessor can initially use the paper version ofthe questionnaire for his convenience, but directly using the electronic version enables immediate discussions with the manager about the LAT/Facility indicators. It is not necessary for the assessor to ask all of the questions; he/she can directly enter some answers according to observations made during the visit. The assessor should ask only the questions to be highlighted (for instance for an educational purpose) or the questions for which the visit cannot provide clear answers. Recommendations for improvement of the laboratory can be made following the discussions.

IMPORTANT: the observations are kept confidential. Establishing a confidential climate will ensure that the assessment flows more smoothly.

3.3.4 Recommendations, analysis of the results and summary

Recommendations should be made following the observation and inspection. It is important to remember that assessments are performed to improve the condition of the laboratory and understand that maintaining good relations between the assessor and the laboratory personnel is vital. Hence, all recommendations and advice should be made in a friendly manner. Comments that may be quite embarrassing or upsetting for the laboratory should only be mentioned to the manager of the laboratory (or the person in charge) at the end of the assessment.

General overview in analyzing indicator summary:

The final analysis of the results by the indicators should be made with the manager of the laboratory who has been collaborating in this assessment. This should be done at the end of the assessment and after entering all data in the LAT/Facility.

It is recommended that the following aspects be noted at the conclusion of the assessment:

- **Weaknesses** of the laboratory, in order to highlight future actions for improvement of the laboratory. The assessor should highlight only the three most important indicators that need to be implemented/improved
- but also **Strengths** of the laboratory, in order to highlight the laboratory's positive aspects.

3.3.5 Mapping of the laboratory

In addition to the usual activities to be performed during the assessment (laboratory visit, filling in LAT/Facility, recommendations, conclusions) it is recommended to draw a map of the laboratory. Once performed, it will be possible to have a look at the entire facility and propose improvements in order to optimize the use of the space allocated.

Equipment needed:
- Telemeter (rapid determination of distances)
- Paper, pen, ruler
- A mapping software

What is expected from the assessor?
- A detailed paper map that includes the names of all rooms (codes can be used for the laboratory equipment but the assessor needs to define each acronym)
- Eventual immediate suggestions for optimization of the premises
- Maps can be computerized later using a software package and improvements can be proposed

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