Laboratory Services in UNHCR-Supported Primary Health Care Facilities

Principles and Guidelines

UNHCR
The UN Refugee Agency

Copies of this document can be obtained from:
UNHCR
Division of Programme Support and Management
Public Health and HIV Section
CP 2500
1202 Geneva, Switzerland
Email: HQPHN@unhcr.org

Cover Photo: Ethiopia / Somali refugees / Kebribeyah refugee camp / Health center funded by UNHCR. Lab Technician Abiyu Tsegaye Gebre, 30 years old, is proceeding a blood test on a refugee. / UNHCR / F. Courbet / December 2008

Graphic Design: Alessandro Mannocchi, Rome

Laboratory Services in UNHCR- Supported Primary Health Care Facilities

Principles and Guidelines

Table of Contents

ACRONYMS 2

INTRODUCTION 3

ROLE OF LABORATORIES IN UNHCR OPERATIONS 4

AIM AND PURPOSE 5

GUIDING PRINCIPLES 6

- Essential Tests 6
- Essential Equipment 8
- Human Resources: staffing requirement, qualifications and training 10
- Laboratory Guidelines/Standard Operating Procedures 11
- Quality Assurance and Quality Control (internal and external) 12
- Laboratories Facilities, Building and Infrastructure 14
- Safety/Biosafety and Infection Control 14
- Communication between Health Staff and Laboratory Staff 15
- Referral and Transport of Essential Specimens 15
- Role of Laboratory in Outbreak Investigation and Management 17
- Disease Surveillance and Health Information System 18
- Procurement, Supply and Maintenance of Laboratory Reagents, Supplies and Equipment 18
- Supervision, Monitorting and Performance Evaluation 18
- Special Concerns regarding TB, Malaria and HIV testing 19
- HIV record keeping and Privacy of Information 20

MONITORING AND EVALUATION TOOL 21

REFERENCES 22

ANNEX 1. CHECKLIST OF RESPONSIBILITIES 24

ANNEX 2. RECOMMENDED LABORATORY LIBRARY 26

ACRONYMS AND ABBREVIATIONS

AFB	Acid Fast Bacilli (includes TB and leprae)
ANC	Antenatal Care
CSF	Cerebro Spinal Fluid
EQA	External Quality Assurance
EQC	External Quality Control
HB	Haemoglobin
HIS	Health Information System
HIV	Human Immunodeficiency Virus
IQC	Internal Quality Control
MSF	Médecins Sans Frontières
MoH	Ministry of Health
PHC	Primary Health Care
PPE	Personal Protective Equipment
PMTCT	Prevention of Mother-to-Child-Transmission
PoCs	Persons of Concern to UNHCR
RDT	Rapid Diagnostic Test
SMS	Supply Management Service
SOPs	Standard Operating Procedures
TB	Tuberculosis
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
VCT	Voluntary Counselling and Testing
WHO	World Health Organization

INTRODUCTION

The United Nations High Commissioner's (UNHCR) health programmes are based on the concept of primary health care (PHC) through which essential health care is made accessible to individuals, families and the community.

Health services are provided to refugees and other persons of concern (PoCs) at national health centres or through health centres supported by UNHCR's implementing and operational health partners.

Accurate and reliable diagnosis is the cornerstone of disease management and control. Laboratories in refugee camps and settlements provide the bulk of available diagnostic techniques and are indispensable in delivery of PHC. A reliable and properly organized laboratory system not only generates information critical to individual case management but also to disease surveillance and control, and outbreak management.

The integration of these clinical laboratories in refugee settings into the national health laboratory structure is of paramount importance for UNHCR to support a functional, coordinated and effective national laboratory network and structure.

This guidance provides key steps on how to achieve reliable laboratory services in UNHCR-supported operations. It is anticipated that the recommendations in this document will be valid until 2015; hereafter a review of the document and the recommendations will be done.

ROLE OF LABORATORIES IN UNHCR OPERATIONS

KEY POINTS FOR STRENGTHENING LABORATORY SERVICES IN UNHCR PROGRAMMES:
AREA OF HIGH PRIORITY :
✓ Quality assurance and quality control (internal and external) ✓ Essential tests ✓ Laboratory guidelines/standard operating procedures (SOPs)
AREA OF IMPORTANCE :
✓ Disease surveillance and health information systems (HIS) ✓ Role of laboratory in outbreak investigation and management ✓ Referral and transport of essential specimens ✓ Human resources

In many refugee camps and settlements and in some urban operations, UNHCR's partners operate basic laboratory services to support the delivery of PHC. These laboratories generally fulfil the criteria of the World Health Organization (WHO) Level I and Level II laboratories; however the service quality varies considerably among operations.

There is currently no uniform standard for delivering quality laboratory services. In most countries where UNHCR operates, the national public health laboratory system is in development and has yet to mature to its full capacity. Therefore, the implementation of laboratory-dependent disease prevention and control programmes has been faced with many challenges.

Significant achievements have been made in Human Immunodeficiency Virus (HIV) laboratory services. However, HIV related services have often advanced independently from other laboratory services that are equally important for the efficient and effective delivery of PHC. These guidelines envision that the gains made in the field of HIV are leveraged to elevate the quality of services provided by the entire laboratory. It emphasizes an integrated approach to comprehensively improve patient care services and to avoid duplication of programmes and efforts so that resources may be utilized effectively.

AIM AND PURPOSE

The overall aim of this guidance is to standardize the procedures and activities of the laboratories and improve the effectiveness, integration and accountability of the laboratory network.

The purposes is to improve procedures to:

- Strengthen the quality of laboratory tests.
- Improve the use and interpretation of laboratory tests by clinicians and public health workers.
- Ensure and establish integration and linkages with the national referral laboratory networks, or where national capacity is not available, with other academic, independent or private institutions.
- Improve laboratory involvement in disease surveillance and outbreak management.
- Ensure timely order, procurement and maintenance of laboratory equipment, reagents and supplies.

Kenya / Kakuma refugee camp / Blood is taken for an HIV test. Kenya / UNHCR / A. Webster / December 2006

GUIDING PRINCIPLES

ESSENTIAL TESTS

Laboratories supported by UNHCR and its partners are to follow the minimum standards for Essential Tests as described in *Table 1*; this is the list of Essential Tests that can be performed in all laboratories in UNHCR-supported operations.

All clinical staff and laboratory staff should be aware of the available tests in the health centre, and use them to ensure proper diagnosis.

All laboratories in UNHCR-supported operations should run at a minimum of a WHO bio safety Level 2[1] defined as:

- Laboratory practices: good microbiological techniques as defined by WHO, plus protective clothing and biohazard sign.
- Safety equipment: open bench, on-site autoclave.

All laboratory staff and clinical staff working in the health centres should be aware of the type of tests that may be referred to the next higher level of laboratory including where and how to send them.

1 Laboratory Biosafety Manual. 3rd edition. World Health Organisation. Geneva. 2004.

TABLE 1: ESSENTIAL TESTS FOR A UNHCR-SUPPORTED LABORATORY	
LABORATORY TEST	TECHNIQUE(S) RECOMMENDED
ESSENTIAL	
Haemoglobin (Hb) estimation colorimetric	HemoCue 301©
Malaria thick and thin blood film (In endemic regions)	Giemsa or field stains
Malaria rapid diagnostic test (in both endemic and non endemic regions) *	Malaria rapid test kits
Blood slide for haemoparasites (trypano, microfilaria, borrelia, leishmania, etc.)	Field stain
Sputum for acid fast bacilli including tuberculosis	Ziehl Neelsen stain
Genito-urinary tract specimens	Wet prep/ gram stain/ KOH (light microscopy)
Urine sediment microscopy	Light microscope
Urine protein and sugar	Multi-parameter reagent dipsticks/strips like Uristix®
Blood glucose	Glucometer with glucose strips-capillary blood-(like Accu-Chek®) Or colorimetric methods -serum or plasma)
HIV screening	Rapid screening tests
Hepatitis B screening	Hep B rapid test
Syphilis screening	RPR/ VDRL carbon antigen
Total white cell count	Manual, using turks fluid
Differential white cell count	Manual, using thin film, reverse field stain
Urine pregnancy rapid test	Beta HCG urine kits

TABLE 1: ESSENTIAL TESTS FOR A UNHCR-SUPPORTED LABORATORY (cont.)

SUPPLEMENTARY	
Cerebro Spinal fuid (CSF) microscopy	Gram/ leishman/ Turks fluid
CSF chemistry	Turbic method
Stool microscopy for parasites	Direct saline, iodine
Blood grouping (if blood transfusion available)	Tile method
Rhesus grouping (if blood transfusion available)	Tile or tube methods
Blood cross-matching/blood compatibility testing (if blood transfusion available)	Tube method
Hepatitis C screening (if blood transfusion available)	Hepatitis C rapid test
Sickle cell screening test (for parts of Africa, India, the Middle East and Mediterranean region)	Sodium metabisulphite
Meningococcal meningitis screening (for Africa Meningitis belt)	Meningococcal meningitis rapid test like Pastorex®
Dengue fever (for countries with high burden of dengue)	Platelet count, Haematocrit
Skin snip/smear/scraping/ lift	Direct microscopy, Ziehl-Neelsen, KOH for fungus, etc.
Stool transport media (specimen transportation to a reference center)	Cary Blair transport media, Amies transport media, etc.
Serum/ blood transportation (eg. measles) (specimen transportation to a reference center)	Tubes with anticoagulant (eg. EDTA), tubes without anticoagulant
CSF transportation media (specimen transportation to a reference center)	Trans-isolate transport media

* In non-endemic regions, the volume of testing conducted is insufficient to maintain laboratory staff competency to read malaria smears.

ESSENTIAL EQUIPMENT

The minimum standards for the essential equipment and supplies are described in *Table 2*, and will apply to all health centres supported by UNHCR and its partners. All equipment on the Essential Equipment List in the column **'Minimum"** of *Table 2* must be available in the laboratory as a minimum standard.

To optimize a laboratory, some equipment listed in the column **"Optimum"**of *Table 2* can be added. UNHCR operations should not procure equipment that are not on the list. Some exceptions may occur, but justification needs to be provided before exceptional approval from the Regional or Global Public Health Officer.

TABLE 2: ESSENTIAL EQUIPMENT FOR A UNHCR-SUPPORTED LABORATORY		
EQUIPMENT NAME	NUMBER NEEDED	
	OPTIMUM	MINIMUM
Binocular microscope powered (12V)	2	1
Autoclave or pressure cooker	1	1
Basic balance/weighing scale	1	1
Manual centrifuge	1	1
Electric centrifuge	1	0
Water filter	1	1
Incubator	1	0
Source of heat (wick stove, hot plate, gas burner, bunsen burner, spirit burner)	3	2
Wire loop with holder	5	2
Glucometer with glucose strips for capillary blood like Accu-Chek®)	1	1
Counting chamber-haemocytometer (improved Neubauer)	4	2
Hand tally counter	2	1
HemoCue 301® and cuvettes (colorimeter or haemoglobin meter 12V)	1	1
Lovibond ® comparator or WHO colour scale	1	1
Refrigerator (with stable electricity)	1	1
Refrigerator (gaz/kerosen if unstable electricity)	1	0
Water bath	1	0
Hot air oven (Kerosene stove)	1	0
Insulated transport box	1	0
Cool packs (for the Insulated transport box)	6	0
Glassware kit	3	2
Batteries (12 volt DC)	2	1
Micro litre pipette (automatic/glass)	3	1
Distillation unit/ water still	1	0
Agitator (rotative, magnetic or vortex)	1	0
Blood bank fridge	1 (if blood transfusion performed)	0

HUMAN RESOURCES: STAFFING REQUIREMENT, QUALIFICATIONS AND TRAINING

The qualifications of laboratory staff for UNHCR-supported operations are:

- Laboratory staff with minimum of two years of training who is permitted to work independently in the laboratory.
- All laboratory staff should be registered and licensed.

Remark: Laboratory staff working in the laboratories with less training or laboratory students must be adequately supervised.

Human resources in UNHCR-supported laboratories will follow the standards described in *Table 3* both in terms quantity and quality/qualifications.

TABLE 3: STANDARDS FOR LABORATORY STAFFING AT UNHCR-SUPPORTED LABORATORIES

Laboratory Technologist (degree)	Laboratory Technician (diploma)	Laboratory Assistant (certificate)	Laboratory Helpers	TOTAL
0	0 but optimally 1	2	1-2	3-4

This should be adapted according to the size of the refugee camp population, the number of laboratories and the level of tests being done; using 2 laboratory staff per 10,000 (optimal) or 15,000 persons (maximum). The average workload should be one qualified technical staff for every 30 tests processed per day (using manual techniques, not rapid diagnostic testing methods).

Laboratory helpers are not recognized as qualified lab staff. This title does not require a Certificate or a Diploma or an official training, but simply an on-the-job training. They can only be recruited as auxiliary support staff in the laboratories and will work under strict supervision. Laboratory helper's functions should be given to refugees as much as possible to encourage community participation and skills development.

UNHCR and its partners will ensure all laboratory staff have the skills and professionalism required for the job.

UNHCR and its partners are committed to staff retention through adequate remuneration in line with national standards for salaries as well as by encouraging a good working environment.

A series of tests could be performed by non-laboratory qualified staff (nurses, HIV counsellor, clinical officer, etc.), but should always be under supervision and should always fall under the final responsibility of the laboratory staff, including quality assurance. The list of possible tests include:

- HIV screening (using rapid tests) such as in voluntary counselling and testing (VCT) programmes, provider initiated counselling and testing for HIV, antenatal clinic for prevention of mother-to-child transmission (PMTCT), health posts and mobile outreach (follow national guidelines, where these exist).
- Hb estimation using HemoCue 301® and its cuvettes (including in surveys).
- Malaria rapid diagnostic tests (including in surveys).
- Dipstick tests for random blood sugar, urinalysis.
- Syphilis screening.

No other tests (including hep B screening tests) should be performed by non-laboratory qualified staff.

Refresher training for laboratory staff should be conducted on a regular basis (at least yearly) through the national laboratory programmes or through expert laboratory stakeholders.

LABORATORY GUIDELINES AND STANDARD OPERATING PROCEDURES

Merely meeting the basic design and safety criteria for diagnostic laboratories are not enough. The laboratory staff must be able to undertake the required tests effectively and accurately and this can only be achieved by following standardized and written procedures/guidelines.

Where national (and up-to-date) SOPs/guidelines for laboratory techniques for health centres/district level laboratories exist, UNHCR-supported laboratories should adopt these.

In countries which are in its early stages of developing standardized SOPs and guidelines for health centres/district level laboratories or with no or outdated national SOPs/

guidelines, at least 1 laboratory guideline/SOP selected from Annex 2 should be present in each UNHCR-supported laboratory.

QUALITY ASSURANCE AND QUALITY CONTROL (INTERNAL AND EXTERNAL)

The performance of the laboratory must be validated and a quality assurance and quality control system must exist. The necessary resources should be made available for this. In all laboratories in UNHCR-supported operations, at least one Quality Assurance Manual or SOPs must be present in the laboratory room (see annex 2).

Laboratories in UNHCR-supported operations must perform internal quality control by establishing routine activities listed below.

It is the responsibility of the laboratory staff to organize and perform these on a regular basis and it is the responsibility of the Medical Coordinator and UNHCR's Public Health Officer to monitor the process:

- All procedures undertaken in the laboratory must be measured against recognized standards. Recognized standards are as an example the positive and/or negative controls given by the manufacturer when the reagents are bought (one can re-order more). All recognized standards to be used are described in the AMREF Quality Assurance Manual (see annex 2).
- New batches of stains or reagents must be validated against the old ones.
- The work of the laboratory staff should be validated regularly by the blind inclusion of known positive and negative specimens in the routine diagnostic work. Laboratory staff should internally organize this by keeping known positive and negative slides for malaria or TB to use among them.

Laboratories in UNHCR-supported operations must participate in external quality control (EQC) activities that are organized nationally, regionally or internationally depending on the country or regional capacities. Each laboratory should at a minimum participate and/or organize at least one EQC. Examples are given below to show which EQC they can participate in or even organize by themselves. They are illustrative, and each country has different options:

- A nationally organized for TB, HIV and malaria. For example in Ethiopia, where the national reference laboratory has 30 different types of proficiency panel testing (HIV rapid tests, haematology, TB, bacteriology, etc.).

- An internationally organized EQC like the WHO/ NCCLS EAREQAS (East Africa Regional EQAS) which covers diseases and tests like microscopy, stool analysis, TB, HIV, syphilis, Hb estimation, liver/renal functions for all level/type of laboratories. WHO provides known positive and negative specimens for assessment of the work of the laboratory.
- Send a selection of the TB slides, malaria smears and HIV rapid test specimens to the countries' regional public health laboratories on a regular defined basis for re-checking and confirmation.
- In countries where none of the above EQC systems exist, UNHCR and partners could organize "stand-alone" EQC scheme. UNHCR's Public Health Officer and partner Medical Coordinator could create groups of 2-4 camps that are geographically close (eg. from the same region or zone). Laboratories from each health facility could send 10 % of their TB slides, malaria slides, HIV screening tests and stool slides to another health facility laboratory for re-checking and feedback. The lists of who, when, and where to send slides to be "re-checked", will be created by each group of laboratories with technical support from their Medical Coordinator and the UNHCR Public Health Officer.

It is the responsibility of UNHCR's Public Health Officer and the partners' Medical Coordinator to ensure the refugee laboratory participates and/or organizes an EQC scheme.

It is the responsibility of the laboratory staff to perform all the activities requested by the EQC scheme they are participating in and to provide feedback their Medical Coordinator, who inform the Ministry of Health (MoH) and the UNHCR's Public Health officer.

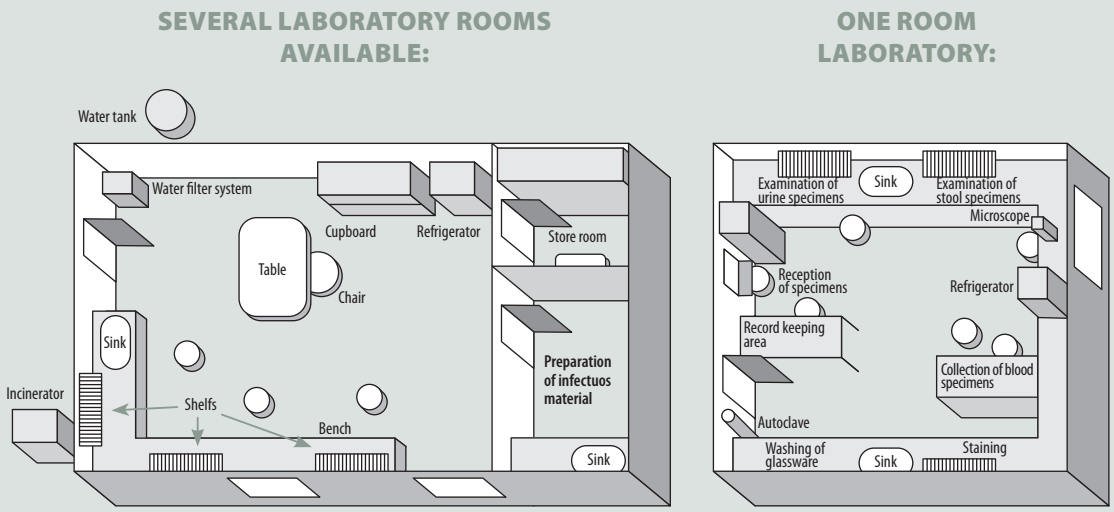
Laboratory staff are primarily responsible for the quality of tests done by the non-laboratory staff in the health facility. Laboratory staff should:

- Supervise on a regular basis these non-laboratory staff testing activities and be given the authority and means to do so by the Medical Coordinator (such as visit health posts for supervision and on the spot training).
- Be responsible for writing and disseminating laboratory procedures/SOPs for these tests to the non-laboratory staff.
- Train and then provide regular refresher trainings every year to the non-laboratory staff.

LABORATORIES FACILITIES, BUILDING AND INFRASTRUCTURE

Where there are no existing laboratory facilities or when UNHCR is to use existing but inadequate laboratory facilities, the minimum standards laboratory facilities should always be met. An overview is given in Figure 1 below.

FIGURE 1: EXAMPLES OF BASIC INFRASTRUCTURE FOR A PRIMARY HEALTH CARE LABORATORY. (SOURCES: WHO EMRO HEALTH LAB FACILITIES IN EMERGENCIES, 1994; WHO MANUAL OF BASIC TECHNIQUES FOR A HEALTH LABORATORY, 2 EDITION, 2003).



SAFETY/BIOSAFETY AND INFECTION CONTROL

Universal precautions should be strictly observed for every collected sample during collection, packaging, storage and transportation of specimens by laboratory staff and non-laboratory staff who are performing rapid testing or people involved in transportation.

Laboratory staff must follow the national biosafety/infection control SOPs or in its absence the AMREF quality manual (see annex 2).

All UNHCR-supported laboratories will ensure safe disposal of laboratory waste by:

- Having a suitable laboratory room/building in place.
- Liquid microbiological waste should be either heat-treated or chemically treated before being discarded into the drainage system. If chemical decontamination is used, any runoff from the drainage system must not be able to contaminate potable water sources.
- All solid waste containing infectious material or potentially infectious material should be incinerated.
- Disposal bins must be provided for sharps and the contents incinerated.

COMMUNICATION BETWEEN HEALTH STAFF AND LABORATORY STAFF

Effective communication between clinical and laboratory staff is an essential component of quality diagnostic services. Team work and delegation of responsibilities between health staff and laboratory staff are crucial.

Health staff must show respect and understanding for the knowledge and skills of their laboratory colleagues.

Health staff should delegate responsibilities to laboratory staff regarding laboratory and diagnostic issues and encourage laboratory staff to be pro-active and active players in the improvement of the health services.

Refresher training on correct use of laboratory test should be organized with laboratory staff and clinical staff together.

REFERRAL AND TRANSPORT OF ESSENTIAL SPECIMENS

The laboratory will not always be able to undertake all the necessary investigations such as proper testing for viral infections or bacterial culture or haemoculture. Therefore, it is important that the laboratory be part of a referral national or regional laboratory network.

Referral of specimens to higher level or to other health centres outside the refugee settlement/camp should be kept to a minimum.

An essential specimen is defined as:

- An outbreak suspicion specimen (e.g. meningitis, watery or bloody diarrhoea, viral haemorrhagic fever).
- Confirmatory testing for HIV.
- Others on agreement with UNHCR's Public Health Officer.

A very strong justification will be required for referrals of patients for laboratory tests only. In this case, the UNHCR Principles and Guidance for Referral Health Care for Refugees and Other Persons of Concerns, 2009 or the country-specific Medical Referral SOPs should be strictly adhered to.

Referral of specimens that are sampled on-site and transported to a higher level is the recommended process to be chosen if referral is needed, especially in case of CD4 testing for HIV.

UNHCR's Public Health Officer and the partners' Medical Coordinator are responsible to ensure that the minimum requirements for the referral of specimens are available, known and applied. Those minimum requirements are:

- Each laboratory must be aware of the type of tests that may be referred to the next higher level of laboratory for processing.
- Laboratories must be provided with the appropriate equipment (e.g. cool boxes and transport media) for the referral of essential specimens.
- Results must be reported within a reasonable length of time from the submitting facility.

ROLE OF LABORATORY IN OUTBREAK INVESTIGATION AND MANAGEMENT

The laboratory plays important roles in confirmation and subsequent management of an outbreak. Laboratories can:

- Confirm syndromic or clinical diagnosis.
  - Help identify treatment options.
  - Help identify control measures.
- Characterize the agent (serotype, biotype, antibiogram, etc.).
  - Evaluate potential effectiveness of treatment.
  - Monitor the spread of a particular clone or subtype.
- Detect an outbreak and confirm the end of the outbreak.

MoHs have the overall responsibility for coordinating and undertaking outbreak investigations including laboratory investigations. UNHCR and its partners should support the MoH by ensuring that the national processes in place for outbreak investigation and management are adhered to.

UNHCR-supported laboratories should be able to collect and prepare specimens (e.g. stool, blood) for transport for outbreak investigation using the correct transport media. In the meningitis belt in Africa, they should also be able to do it for CSF specimens. All the relevant transport media should be procured with other lab reagents and supplies (see *Table 1*: Essential tests for a UNHCR-supported laboratory).

Outbreak suspicion reporting process: it is the responsibility of the laboratory staff to report any outbreak suspicion immediately to the Medical Coordinator, who in turn informs UNHCR's Public Health Officer.

UNHCR's Public Health Officer, in collaboration with MoH, is responsible to follow the specimen when one is referred to central level to ensure timely feedback of the results to the refugee camp/settlement.

It is the responsibility of the UNHCR Public Health Officer to create and regularly update the list and contact numbers of the national, regional and international laboratories for confirming priority diseases and conditions.

An MoH Rapid Response Team usually overseas the issues of emergency and epidemics response. It is key to ensure that the laboratory staff are part of this Rapid Response Team to advice on the best specimen to collect and the best test to perform.

DISEASES SURVEILLANCE AND HEALTH INFORMATION SYSTEM (HIS)

In countries where UNHCR operates, there could be different surveillance systems in place in to which a UNHCR-supported laboratories might participate:

1) The national disease surveillance system organized by the MoH defines immediate and/or weekly reportable diseases/conditions.

2) UNHCR's HIS has an early warning component, that has its own standardized reporting formats and indicators.

PROCUREMENT, SUPPLY AND MAINTENANCE OF LAB REAGENTS, SUPPLIES AND EQUIPMENT

It is UNHCR's policy to principally bid and purchase medical products through international suppliers (see *UNHCR Essential Medicines and Medical Supplies, Policy and Guidance, 2011).*

Local/regional procurement is to be exceptional. Local/regional procurement requires special authorization from supply management service (SMS) Budapest and UNHCR's Regional or Global Public Health Officer.

Laboratory reagent and equipment requests should appropriately reflect the situation on the ground. The list of essential equipment required is described in table 2 Essential Equipment in this guidance.

Laboratory staff are responsible for the care and maintenance of laboratory equipment. The purpose is to ensure that a particular instrument is properly used, maintained and calibrated such that any data generated from it is considered reliable.

SUPERVISION, MONITORING AND PERFORMANCE EVALUATION

Supervision, monitoring and performance evaluation of UNHCR-supported laboratories falls under the responsibilities of two different actors with different tasks:

- UNHCR and the health partner.
- The Ministry of Health.

The Medical Coordinator of the partner and UNHCR's Public Health Officer are responsible for field monitoring and to ensure that standards are adhered to in all laboratories.

The MoH has the responsibility to technically supervise the laboratory staff and coordinate the laboratory system including referrals of specimen and maintenance of equipment. But their capacity may be limited in some countries. UNHCR should work towards strengthening the MoH's capacity for supervision of laboratory services.

SPECIAL CONCERNS REGARDING TB, MALARIA AND HIV TESTING

HIV, malaria and TB testing quality assurance: testing quality assurance measures must be in place in refugee camps/settlements; whether through participation in a national EQC scheme, a national HIV proficiency testing programme or regional or international programmes.

HIV, malaria and TB rapid test kits: besides the classical diagnostic methods, the 3 diseases can be screened/diagnosed using rapid diagnostic test (RDT) kits which can be useful in UNHCR operations to improve access to testing and diagnosis. The advantages of rapid tests are numerous but several practical considerations and issues concerning the accuracy of test kits and testing algorithms need to be taken into account.

HIV Testing: non-laboratory staff (like the HIV counsellors) that perform HIV testing should be included in a quality assurance programme. UNHCR and partners should explore with the MoH how they can be included in such programmes.

HIV, malaria and TB testing procedures: laboratory staff should be formally trained in the proper running of tests and not rey solely on the package inserts or self-made SOPs to guide them. This training is needed to understand the implications of not following recommended procedures and to document when those procedures are not followed.

HIV, malaria and TB testing algorithms: approved national HIV, malaria or TB testing algorithms should be strictly followed.

HIV Testing Algorithms: HIV counsellors and other health staff should never violate the approved HIV testing algorithm. To address this, UNHCR and partners will:

- Ensure that refugee settlements/camps are included in national HIV testing quality assurance/ quality control programme.

- Conduct periodic joint supportive supervisory missions with MoH and other partners.
- Ensure an adequate supply of HIV test kits at all times.
- Ensure regularly supervision by the laboratory staff where HIV testing is conducted by non-laboratory staff.
- Conduct HIV testing refresher training for all staff performing testing including the antenatal care staff and HIV counsellors.

HIV RECORD KEEPING AND PRIVACY OF INFORMATION

- A proper filing system for HIV records should be established taking into account especially dates, names, month, year, test(s) used.
- A standardized laboratory logbook should be implemented to facilitate tracking of test kit performance and testing performance. Ensure that test batch number and expiry dates of each kit are included.
- Client laboratory results and records should be stored securely and only accessible to those who need to review the records.

MONITORING AND EVALUATION TOOL (FOR LABORATORY AND NON-LABORATORY STAFF)

The UNHCR laboratory monitoring and evaluation tool is an evaluation tool designed for laboratory staff and public health officers to jointly:

- Assess the laboratory in a standardized way.
- Automatically generate numerical indicators related to laboratory capacities.
- Follow the improvement of the same laboratory over time.

The monitoring and evaluation tool is available on the UNHCR HIS website, http://his.unhcr.org. A complete assessment of a laboratory using this tool will take approximately 2 hours. The assessment must be carried out during opening hours in order to be able to observe staff at work.

The system will automatically analyze the results of the indicators entered into the system and provide a grading for each of the areas. Both the positive and negative results should be discussed with the laboratory and public health team and a plan developed accordingly.

REFERENCES

1. UNHCR 's Principles and Guidance for Referral Health Care for Refugees and Other Persons of Concern, December 2009. http://www.unhcr.org/cgibin/texis/vtx/search/?page=&comid=4b4c8da19&keywords=pubhealth-strategies&policies

2. UNHCR's Essential Medicines and Medical Supplies, Policy and Guidance, UNHCR, 2011. http://www.unhcr.org/cgi-bin/texis/vtx/search/?page=&comid=4b4c8da19&keywords=pubhealth-strategies&policies

3. UNHCR Epidemic Preparedness and Response in Refugee Camp Settings, A pocket guide for Public Health Officers, 2011. http://www.unhcr.org/cgibin/texis/vtx/search/?page=&comid=4b4c8da19&keywords=pubhealth-strategies&policies.

4. UNHCR/WHO/UNAIDS, Policy Statement on HIV Testing and Counselling in Health Facilities for Refugees, Internally Displaced Persons and other Persons of Concern to UNHCR, 2009. http://www.unhcr.org/4b508b9c9.html

5. The Maputo Declaration on Strengthening of Laboratory Systems. Maputo, Mozambique: World Health Organization; January, 2008. http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf

6. World Health Organization. Manual of Basic Techniques for a Health Laboratory. 2nd edition, WHO, Geneva 2003. http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codcch=2120

7. World Health Organization. Guidelines on regulations for the transport of infectious substances & diagnostic specimens. WHO 2005. http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22r%20.pdf

8. Transport of infectious substances. World Health Organization,Geneva. 2004. WHO/CDS/CSR/LYO/2004.9. http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22r%20.pdf

9. Laboratory Bio safety Manual. 3rd edition. World Health Organization. Geneva. 2004. http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

10. Cheesbrough M. District Laboratory Practice in Tropical Countries. Part 1 & 2. 2nd Edition. Cambridge University Press 2005

11. MSF International. Draft Practical guide for laboratory workers: Laboratory manual, First edition, Draft 2010. Personnal communication with MSF.

Zambia / Angolan refugees / Mayukwayukwa camp / The laboratory at the camp clinic, checking for malaria. It treats both Angolan refugees and local Zambians as part of the Zambia Initiative, which could ease the local integration of those Angolans who do not want to repatriate. / UNHCR / J. Redden / 9 March 2006

ANNEXES

ANNEX 1. CHECKLIST OF RESPONSIBILITIES

SUMMARIZES "WHO MUST DO WHAT" FOR LABORATORY OPERATIONS IN UNHCR OPERATIONS

GUIDING PRINCIPLE	WHAT TO DO	WHO IS RESPONSIBLE	WHO IS INVOLVED
1	Essential tests	• Health Centre (HC) Medical Officer	• HC Laboratory Staff • HC Clinical Officer+Nurses • UNHCR Public Health Officer • Medical Coordinator
2	Essential equipment	• Partner Medical Coordinator	• UNHCR Public Health Officer • HC Laboratory Staff
3	Human resources	• Partner Medical Coordinator	• UNHCR Public Health Officer
4	Laboratory guidelines/ SOPs	• UNHCR Public Health Officer	• HC Medical Officer • HC Laboratory Staff
5	Quality Control (internal and external)	• Partner Medical Coordinator • Laboratory staff	• HC Medical Officer • UNHCR Public Health Officer
6	Laboratories facilities, building and infrastructure	• Partner Medical Coordinator	• HC Laboratory Staff • UNHCR Public Health Officer
7	Safety/biosafety and infection control	• Partner Medical Coordinator	• HC Laboratory Staff • HC Clinical Officer+Nurses • UNHCR Public Health Officer

ANNEX 1. CHECKLIST OF RESPONSIBILITIES (cont.)

SUMMARIZES "WHO MUST DO WHAT" FOR LABORATORY OPERATIONS IN UNHCR OPERATIONS

GUIDING PRINCIPLE	WHAT TO DO	WHO IS RESPONSIBLE	WHO IS INVOLVED
8	Communication between clinical and laboratory staff	• Partner Medical Coordinator	• HC Laboratory Staff • HC Clinical Officer+Nurses • UNHCR Public Health Officer
9	Referral and transport of essential specimens	• Partner Medical Coordinator	• HC Laboratory Staff • UNHCR Public Health Officer
10	Laboratory role in outbreak investigation and management	• Partner Medical Coordinator	• HC Laboratory Staff • UNHCR Public Health Officer • Medical Coordinator
11	Diseases surveillance, health information systems	• Partner Medical Coordinator	• HC Laboratory staff • Partner Medical Coordinator • UNHCR Public Health Officer
12	Procurement of lab reagents/supplies, equipment and maintenance	• UNHCR Public Health Officer	• HC Laboratory staff • HC Medical Officer • Partner Medical Coordinator
13	Supervision, performance evaluation	• Partner Medical Coordinator	• UNHCR Public Health Officer
14	Financing and accountability	• Partner Medical Coordinator	• UNHCR Public Health Officer
15	Regulatory framework	• UNHCR Public Health Officer	• Partner Medical Coordinator

ANNEX 2. RECOMMENDED LABORATORY LIBRARY

The following guidelines should be available in each laboratory for Standard Operating Procedures:

- National laboratory manuals

And one of the following guidelines:

- Practical Laboratory Manual for Health Centres. AMREF Publication .J Carter, O Lema. 2011 version (recommend guidance) http://www.amref.org/info-centre/online-store/?sectionid=9&page=6
- Manual of Basic Techniques for a Health Laboratory. 2nd edition, World Health Organization, Geneva 2003. http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codcch=02120

Further recommended guidelines are:

- Laboratory Biosafety Manual. 3rd edition.. Geneva, 2004. http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf
- Standard Operating Procedures for Essential Laboratory Tests. AMREF. 2004. http://www.amref.org/info-centre/online-store/?sectionid=9
- Guidelines on Specimen Collection, Storage and Transportation. AMREF,2004.
- Standard Operating Procedures for Care and Maintenance of Laboratory Equipment. AMREF. 2004
- Standard Operating Procedures on Laboratory Utilisation for Clinicians. AMREF. 2004.

Quality assurance

The manual below is recommended AND should be procured where there are no national manuals on Quality Assurance or where the national manual are not up-to-date:

- Quality manual for clinical and laboratory diagnostic services, AMREF, 2004. http://www.amref.org/info-centre/online-store/?sectionid=9&page=2

The WHO reference manual for Quality Assurance for Malaria, TB and HIV are:

- Malaria microscopy quality assurance manual - version 1. World Health Organization 2009. http://www.who.int/malaria/publications/atoz/mmicroscopy_qam/en/index.html.
- Laboratory Services in Tuberculosis Control. Part 1 Organization and management. World Health Organization 1998. See Chapter 7. http://wwwn.cdc.gov/dls/ila/documents/lstc1.pdf
- Guidelines for organizing national external quality assessment schemes for HIV serological testing, World Health Organization 1996. http://www.who.int/diagnostics_laboratory/quality/en/EQAS96.pdf

The WHO reference manuals for rapid diagnostic testing for each disease are:

- Roadmap for rolling out Xpert mtb/rif for rapid diagnosis of TB and MDR-TB, December World Health Organization, 2010. TB diagnostics and laboratory strengthening. http://www.who.int/tb/laboratory/roadmap_xpert_mtb-rif.pdf
- Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests (RDTs), World Health Organization 2010. http://www.who.int/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf
- Guidelines for use in HIV testing and counselling services in resource-constrained settings. World Health Organization 2004. http://www.emro.who.int/aiecf/web28.pdf

UNHCR
The UN Refugee Agency