DEPARTMENT OF NATIONAL HEALTH LABORATORY

AND

DIAGNOSTIC SERVICES

THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH

NATIONAL LABORATORY GUIDELINES FOR PREPAREDNESS AND RESPONSE TO PUBLIC HEALTH EMERGENCIES

March 2024

Foreword

These National Laboratory Guidelines for Preparedness and Response to Public Health Emergenciesthe first version to be developed in Uganda - seek to provide easy-to-use practical, complete and useful information on laboratory roles and processes in Public Health Emergency Management.

The Ministry of Health recognizes the importance of public health in its pursuit of the unmet goal "To accelerate movement towards Universal Health Coverage (UHC) with essential health and related services needed for promotion of a healthy and productive life". Response to public health emergencies can efficiently contribute to the realisation of this goal only when it is well-coordinated basing on standardised guidelines.

The National Laboratory guidelines for preparedness and response to public health emergencies provide standardised procedures to ensure effective laboratory coordination during preparedness and response to public health concerns.

The Ministry of Health remains committed to strengthening public health interventions. All stakeholders and partners are encouraged to consult these guidelines to inform their contribution to the public health innovations.

Dr. Charles Olaro
For DIRECTOR GENERAL HEALTLH SERVICES

Acknowledgement

On behalf of the department of National Health Laboratory and Diagnostic services (NHLDS), I would like to acknowledge the immense financial and technical support received from our development partners particularly Centres for Disease Control and Prevention (CDC), World Health Organisation (WHO) and the Implementing Partner, Infectious Diseases Institute (IDI). I extend our sincere appreciation to the other Ministries (Ministry of Water and Environment, Ministry of Tourism, Wildlife and Antiquities, Ministry of Agriculture, Animal Industry and Fisheries, Ministry of Internal Affairs, Ministry of Defence and Veteran Affairs) and other government departments for their technical input, collaboration and tireless efforts in development and finalization of this document. Particularly I want to acknowledge the efforts of the individuals below for steering this process and their invaluable technical input.

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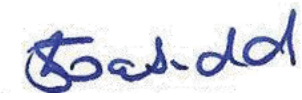
The department is happy to implement these guidelines to support our preparedness and response efforts towards averting the emerging and re-emerging infectious disease out breaks through providing real time confirmation, characterisation and monitoring of prognosis.



Dr. Nabadda Susan

Commissioner, National Health Laboratory and Diagnostic Services (NHLDS) Ministry of Health

Abbreviations and Acronyms

AFI-NISS	Acute Febrile Illness - National Integrated Surveillance System)
AHPC	Allied Health Professionals Council
AMR	Antimicrobial Resistance
CDC	Centers for Disease Control and Prevention
COVAB	College of Veterinary Medicine Animal Resources and Biosecurity
CPHL	Central Public Health Laboratories
DHO	District Health Officer
DLFPs	District Laboratory Focal Persons
DVL	District Veterinary Laboratories
GHSA	Global Health Security Agenda
HSD	Health Sub-District
HSSP	Health Sector Strategic Plans
IC	Incident Commander
IDI	Infectious Diseases Institute
JCRC	Joint Clinical Research Center
JEE	Joint External Evaluation
LIMS	Laboratory Information Management Systems
LLP	Lab Leadership Program
LTC	National Health Laboratory Technical Advisory Committee
MoH	Ministry of Health
MOH	Ministry of Health
MRC	Medical Research Council
NADDEC	National Animal Disease Diagnostic and Epidemiology Centre
NAPHS/A	National Action Plan for Health Security Acceleration
NEQAs	National External Quality Assessment Scheme
NHLDS	Department of National Health Laboratory and Diagnostic Services.
NMRL	National Microbiology Reference Laboratory

NMRL	National Microbiology Reference Laboratory
NMS	National Medical Stores
NPHL	National Public Health Laboratory
NSTRN	National Sample Results Transport Network
NTLP	National Tuberculosis and Leprosy Program
NTRL	National Tuberculosis Reference Laboratory
PEPFAR	President's Emergency Plan for AIDS Relief
PHEOC	Public Health Emergency Operation Centre
PHFP	Public Health Fellowship Program
PHS	Public Health Surveillance
PIO	Performance Improvement Officer
PNFP	Private not for Profit
POCT	Point of care testing
POEs	Border Points of Entry
QMS	Quality Management Systems
RADDEC	Regional Animal Disease Diagnostic and Epidemiology Centre
TA/PM	Technical Advisor / Project Manager
TWG	Technical Working Group
UBTS	Uganda Blood Transfusion Service
UMLTA	Uganda Medical Laboratory Technology Association
UNCST	Uganda National Council for Science and Technology
USAID	United States Agency for International Development
UVRI	Uganda Virus Research Institute
VHT	Village Health Team
WHO	World Health Organization

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1.0 BACKGROUND

1.1 Introduction

Countries worldwide are frequently challenged with Public Health Emergencies of International Concern (PHEICs) with World Health organisation (WHO) declaring seven since the beginning of the 21st century (01st January, 2001). Examples of these PHEICs include 2009 H1N1 influenza pandemic, West African Ebola outbreak from 2013 to 2015, Poliomyelitis outbreak from 2014, Zika virus outbreak of 2016, Ebola outbreak in Democratic Republic of Congo from 2018 to 2020, COVID-19 pandemic since 2020, and Monkey pox outbreak of 2022. These PHEICs and other emerging health challenges have exposed gaps and fragmentation in health systems with limited public health capacities and governance[1].

The WHO African region has registered the heaviest burden of public health emergencies; with Uganda in the last ten years registering multiple outbreaks such as Ebola Sudan Virus Disease (2022), Ebola Zaire (2018), Marburg (2017), Yellow Fever (2022), Crimean Congo Haemorrhagic fever (CCHF), Rift Valley Fever (RVF), Plague, Anthrax, Rabies, Brucellosis, Trypanosomiasis, and Avian Influenza[2]. Furthermore in 2018 alone, Uganda registered the most occurrence of infectious disease outbreaks in the WHO Africa Region[3]. This is basically because, Uganda lies within the Yellow Fever, Meningitis, and filovirus triangle/belts of sub-Saharan Africa hence prone to such outbreaks. The other predisposing factors are the numerous porous borders and large number of persons living in close proximity to animals which often expose the populace to these public health emergencies of zoonotic, emerging and or re-emerging infectious diseases[4]. These outbreaks are also exacerbated by a large number of persons involved in international trade, trans-boundary mass population movements and inadequate surveillance and inadequate response capacity of the country at the animal-human interface.

Public health emergency burdens negatively impact health and economic systems, food safety and food security, social impacts on vulnerable populations including refugees and other related socio-economic impacts[5]. In many cases, such emergencies are preventable and even controllable with proven public health interventions but, without essential support, they will continue to cost lives, overwhelm health systems and fuel socio economic disruption[6]. The prevention and control of these public health emergencies is greatly enhanced by the capacity of the laboratory to efficiently detect, characterise and trace disease transmission.[7] The role of the laboratory in disease outbreaks as well as prevention and control of public health emergencies is highlighted in a number of national policy documents including the Uganda's National Action Plan for Health Security (2019-2023) that

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[1] https://www.who.int/publications/i/item/9789240038929

[2] http://library.health.go.ug/publications/policy-documents/uganda-one-health-strategic-plan-2018-2022

[3] Infectious disease outbreaks in the African region : Overview of events reported to the World Health Organisation in 2018

[4] http://library.health.go.ug/publications/work-plans/national-action-plan-health-security-2019-2023-0

[5] https://reliefweb.int/report/world/ensuring-health-security-african-region-emergency-preparedness-and-response-flagship-programmes

[6] https://www.who.int/publications/m/item/who-global-health-emergency-appeal-2022-regional-summary-african-region

[7] WHO AFRO Guide for Public Health Laboratory Networking To Strengthen IDSR

highlights the need to expand capacity to detect and share results of all ten WHO Core tests, including priority zoonotic diseases[8] and the National Technical Guidelines for Integrated Disease Surveillance and Response (3rd Ed) that emphases the need to strengthen timely detection of public health emergencies[9]. In order to achieve this, the Uganda's Ministry of Health through the department of National Health Laboratory and Diagnostic Services (NHLDS) focuses on availability and accessibility of Quality Laboratory services[10]. However, there is no dedicated laboratory guideline that addresses the entire continuum of laboratory coordination, operations, and collaborations during preparedness and response to public health emergencies. With the growing concern of Public Health Emergencies, National Laboratory Guidelines for Preparedness and Response to Public Health Emergencies are crucial in providing guidance to enable prevention, early detection of, and rapid response to infectious disease threats that can cause public health emergencies.

1.1.1 National Laboratory Strategy in Preparedness and Response to Public Health Emergencies

The laboratory strengthening strategy covers five broad thematic areas i.e.;

i. Coordination of public health laboratory and surveillance activities for both national and sub national levels
ii. Competency and skill set development amongst laboratory staff
iii. Collection, packaging, referral, and testing of samples for confirmation of epidemic-prone diseases
iv. Licensing and regulation of laboratories and laboratory staff, quality assurance, biosafety and biosecurity practices
v. Collection, analysis, and reporting of laboratory data and information for public health action

To ensure efficiency, public health laboratories are aligned within a national public health laboratory network (NPHLN) i.e. district, sub national, national, regional and international laboratory networks with clear guidelines.

1.2 Purpose

The purpose of these guidelines is to provide easy-to-use practical, complete and useful information on laboratory roles and processes in Public Health Emergency Management. This will provide high quality, accurate and timely laboratory-based information for public health decisions directed at effective control and prevention of priority diseases.

1.2.1 Objectives

The objectives of these guidelines include;

1. To describe the public health laboratory structures and their roles in Public Health Emergency management.
2. To describe the laboratory processes involved in effective preparedness and response to Public Health Emergencies.
    i. Laboratory-based surveillance

[8] http://library.health.go.ug/publications/work-plans/national-action-plan-health-security-2019-2023-0
[9] National Technical Guidelines for Integrated Disease Surveillance and Response Third Edition 2022
[10] https://www.ahpc.ug/UGANDA%20NATIONAL%20HEALTH%20LABORATORY%20SERVICES%20POLICY.pdf

ii. Quality Assurance
iii. Biosafety and Biosecurity
iv. Laboratory Human Resource Management and Welfare
v. Data Use and Information Management
vi. Monitoring and Evaluation

3. To describe the laboratory confirmation of causative agents and prognosis for priority Epidemic prone diseases.

1.3 Situation analysis of National Laboratory Preparedness and Response in Uganda

1.3.1 Current Laboratory Testing Capacities

Uganda has a total of 12 national reference and referral laboratories able to detect public health events. These include;

Human Health laboratories

1. Central Public Health Laboratories (CPHL) for malaria, haematology, and Early Infant Diagnosis/Viral Load (EID/VL)-Butabika, Kampala.
2. National Tuberculosis Reference Laboratory (NTRL) for TB testing- Butabika, Kampala;
3. National Microbiology Reference Laboratory (NMRL) for microbiology testing- Butabika, Kampala;
4. Uganda Virus Research Institute (UVRI) for Viral Haemorrhagic Fever (VHF), viral respiratory syndrome, arbovirus, plague, and HIV testing-Entebbe;
5. Mulago National Referral Hospital Sexually Transmitted Disease (STD) Reference Laboratory for STD testing-Mulago, Kampala;
6. Mulago National Referral Hospital Pathology/Histopathology laboratory for histopathology procedures- Mulago, Kampala;
7. Department of Government Analytical Laboratories (DGAL) for forensic testing (serves as the National Poison Centre)-Wandegeya, Kampala;
8. Uganda Blood Transfusion Services (UBTS) for blood-borne pathogen testing-Nakasero, Kampala;

Animal health laboratories

1. National Animal Disease Diagnostic and Epidemiology Centre (NADDEC) for *List A* and *List B World Organisation for Animal Health (WOAH)* diseases-Entebbe;
2. Queen Elizabeth National Park Laboratory, Mweya for wildlife animal testing-Kasese.

Plant health laboratories

1. National Crop Resources Research Institute (NaCRRI) for crop disease testing-Namulonge.

Water and Environment health

1. National Water Quality Reference Laboratory for water quality testing-Entebbe.

Note: In each of these sectors, the respective national reference laboratories exist as part of a tiered national laboratory service delivery structure described in *section 2*.

The country has two Biosafety level III laboratories based in Makerere University, College of Veterinary Medicine, Animal Resources and Biosecurity (Animal health) and the Epicentre Mbarara Research Centre laboratory (Human health).

For international laboratory testing there is an existing Memorandum of Understanding (MoU) for transportation of special pathogen samples to the Centres for Disease Control and Prevention (CDC) - Atlanta, USA and the National Institute of Health (NIH), South Africa. Samples are also referred to WHO supranational reference laboratories for testing.

1.3.2 Limitations in Laboratory Preparedness and Response

While several guiding documents that address aspects relevant to preparedness and response exist, there has been no comprehensive document guiding the laboratory component of preparedness and response to Public Health Emergencies. Laboratory preparedness and response interventions have typically been reactive, quickly improvised in the context of rapidly escalating public health emergencies. While this flexibility is an asset in public health emergency management, the *ad hoc* nature of these improvised interventions has posed challenges for preparedness and response like:

- Limited laboratory preparedness and readiness for public health emergencies, making it difficult to put together a well-coordinated, truly cohesive response in a timely manner;
- Delayed activation of the laboratory sub-components necessary for response due to limited preparedness and readiness for the concerned public health emergency. Such sub-components include:
    - Human resource deployment;
    - Dispatch of laboratory equipment, supplies, consumables, and reagents;
    - Designation of testing sites.
- Duplication of existing systems and structures while setting up the response to the concerned public health emergency, leading to fragmentation of outcomes. Such systems and structures include:
    - Outbreak data and information systems
    - Staff structures (routine structures versus response structures)
- Limited sustainability of laboratory preparedness and response interventions due to limited anchorage in mainstream laboratory service delivery.

1.3.3 Laboratory Assessments for Preparedness and Response Capacities

In 2017, Uganda underwent a Joint External Evaluation (JEE) of its International Health Regulations (2005) [IHR (2005)] capacities[12]. The National Laboratory System technical area was among the IHR (2005) capacities evaluated. Under this technical area, four indicators were assessed and the scores (out of a possible 5); were as shown below:

Indicator No.	Indicator	Score
D.1.1	Laboratory testing for detection of priority diseases	4/5
D.1.2	Specimen referral and transport system	3/5

D.1.3	Effective modern point-of-care and laboratory-based diagnostics	3/5
D.1.4	Laboratory quality system	3/5

Source: Uganda 2017 JEE Report[11].

The evaluation took stock of progress, identified challenges and informed the development of the NAPHS 2019 - 2023 which emphasised the need to expand capacity to detect and share results of all ten WHO Core tests, including priority zoonotic diseases.

Following three years of NAPHS implementation, the country conducted an internal multi-sectoral self-assessment of its IHR (2005) capacities in 2021. The findings of this self-assessment revealed that the scores in the four indicators were as follows:

Indicator No.	Indicator	Score[13]
D.1.1	Laboratory testing for detection of priority diseases	4/5
D.1.2	Specimen referral and transport system	4/5
D.1.3	Effective modern point-of-care and laboratory-based diagnostics	3/5
D.1.4	Laboratory quality system	3/5

The score in Indicator D.1.2 improved from 3 to 4 and remained the same for the other indicators.

However, the findings also revealed that some human and animal laboratories lack the capacity to run quality assurance systems. Persistent gaps in diagnostic services in animal health (NADDEC) were noted. The poor performance in these areas was largely attributed to inadequate funding for priority areas within the National Laboratory System technical area and weak coordination mechanisms at the regional and sub-national levels.

[11] Joint External Evaluation of IHR Core Capacities of the Republic of Uganda, Mission report, June 26-3,2017

1.4 Legal Policy Frameworks

Uganda as a signatory to the IHR 2005 is obliged to build its capacity to prevent, detect and respond to Public Health Emergencies at source[12]. Uganda has a favourable policy environment for implementation of National Laboratory Guidelines for Preparedness and Response to Public Health Emergencies. The Public Health Act (CAP 281) and Animal Diseases Act guide laboratory components for preparedness and response activities for all Public Health Emergencies. The National Policy for Disaster Preparedness and Management (2010) has provisions for strengthening the capacity to prevent, detect and respond to public health emergencies. The Second National Health Policy (2010) and the Health Sector Development Plan 2020/21-2025/26 also have provisions for strengthening laboratory services at all levels to provide basic, complementary, referral and specialist laboratory services. It emphasises that the laboratory quality management system in health facilities and Public Health Reference Laboratories are established.

In addition, the Uganda National Health Laboratory Services Policy II, provides a framework for implementation of Laboratory Preparedness and Response activities in the Ministry of Health Sector. The National Laboratory Guidelines for Preparedness and Response to Public Health Emergencies have been developed in line with the international, WHO AFRO- and national legal frameworks/policies in relation to public health emergencies as indicated in the table below. For details of the contribution of the policies refer to annex 1.

Table 1: Showing International and National Legal Frameworks for public health

International	National
– Africa 2 Africa Health Strategy (2016-2030) – Agenda 2030 - Sustainable Development Goals – East Africa Community – (EAC Vision (2050) – Global Health Security Agenda – Guide for National Public Health Networking to strengthen Integrated Disease Surveillance and Response (IDSR) (2008) – Integrated Disease Surveillance and Response (IDSR) – International Health Regulations (2005) – Regional Strategy for Health Security and emergencies 2016	– 3rd Edition Integrated Disease Surveillance and – Response (IDSR) – Animal Diseases Act Chapter 38 laws of Uganda – Delivery of Veterinary Services policy (2002) – Health Sector Development Plan (2015/16-2019/20) – National Action Plan for Health Security (NAPHS) 2019-2023 – National Development Plan (NDP) III (2020/21 – 2024/25) – National Health Policy II (2010 – 2020) – National Policy for Disaster Preparedness and – Management 2011 – Parish Development Model 2021 – Plant Protection Act – The Local Government Act 1997 – The National Environment Act 2019 – The Public Health Act (1935) amendment bill 2022 – The Uganda National One Health Strategic Plan (2018-2022) – Uganda Vision 2040 – Uganda Wildlife Act, 2019 – Water Act Cap 152

[12] https://www.who.int/publications-detail-redirect/9789241580496

Standard Operating Procedures to support Tools to aid laboratory stakeholders in performing their functions shall be developed/updated.

1.5 Target Audience

This guideline is intended for use by laboratory management in districts, sub national and national levels. It is also to be used by public health emergency operations centre, office of the Prime Minister (Department of Disaster), One Health stakeholders and other relevant stakeholders who contribute directly or indirectly to emergency preparedness and response to public health emergencies. Other users of this guide may include communities, human and animal health workers, emergency responders, leaders, policy makers, ministries, departments and agencies, development and implementing partners, training institutions, civil society organisations, academia and the private sector. The guide will be also be useful for the private laboratory sector to understand the response and preparedness during PHE.

2.0 LEADERSHIP, ORGANISATION AND COORDINATION

Laboratory services in Uganda exist in a continuum both within and across the various sectors.

2.1 Laboratory structures within sectors

Within sectors, laboratory services are organised into and delivered through a tiered structure with defined minimum service delivery packages provided at the different levels of service delivery. The figure below illustrates this tiered structure, highlighting referral, reporting, technical support, supervision and feedback within sectors.

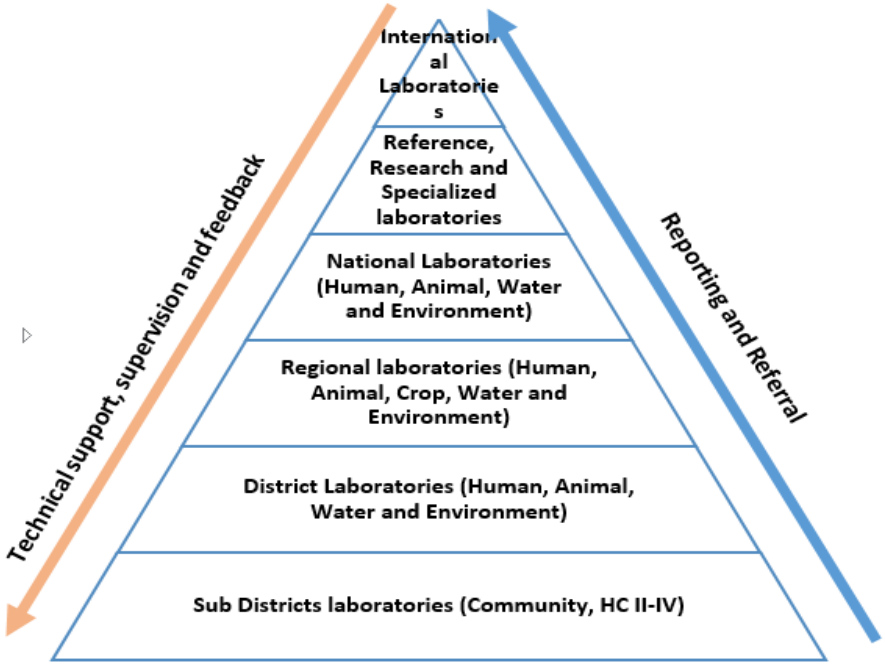


Fig 1: Hierarchy of National Laboratory Service delivery

2.2 Laboratory structure across sectors

Laboratory services in Uganda also exist in a continuum across various sectors which include the human, animal, plant, and environmental health sectors.

2.2.1 Human Public Health

Human public health laboratory services are coordinated by the Department of National Health Laboratory and Diagnostic Services under the Directorate of public health of the Ministry of Health. The Department directly coordinates laboratories at six different levels with varying capacities for Human Resource, Equipment and Infrastructure.

The varying levels in the public health laboratory service delivery include:

i. National Specialised Reference Laboratories namely NHLDS, UVRI, UBTS, Directorate of Government Analytical Laboratories (DGAL), the National STD Reference Laboratory, the Joint Clinical Research Centre (JCRC), Uganda Cancer Institute (UCI), Mulago Histopathology Laboratory, Uganda Heart Institute (UHI) and Entomology Reference

Laboratory. Specialised Laboratories of Development/implementing partners, and Academia Laboratories.

ii. National Referral Hospital laboratories such as Mulago, Butabika, Kiruddu, Kawempe, and Naguru.
iii. Regional referral Hospital Laboratories (16)
iv. General hospital laboratories (53)
v. Health centre IV laboratories (195)
vi. Health centre III laboratories (1269)

Note: The Private sector (Private not for profit-PNFP/Private for profit-PFP), Development and Implementing partner laboratories are the other service delivery points interlinked to the public laboratories.

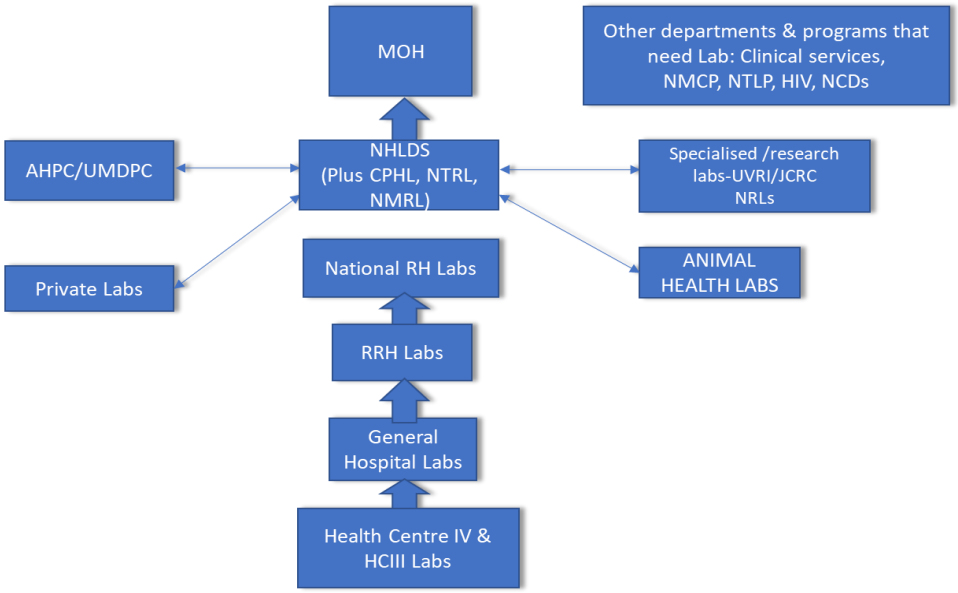
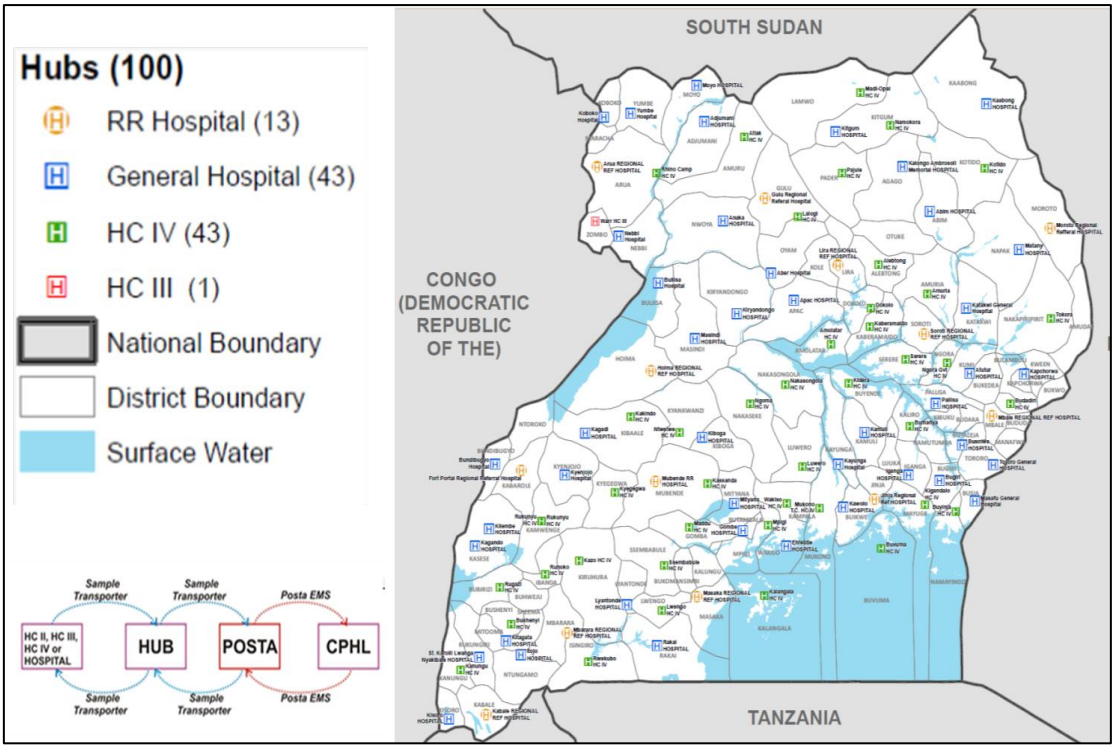


Fig 2: Human Health Laboratory network

The capacity of 100 of the above laboratories-designated as hub laboratories-has been enhanced in terms of Human resource, infrastructure and equipment to enable them perform basic tests and coordinate sample referral[13].

[13] Guidelines for the Uganda National Health Laboratory Hub and Sample Transport Network



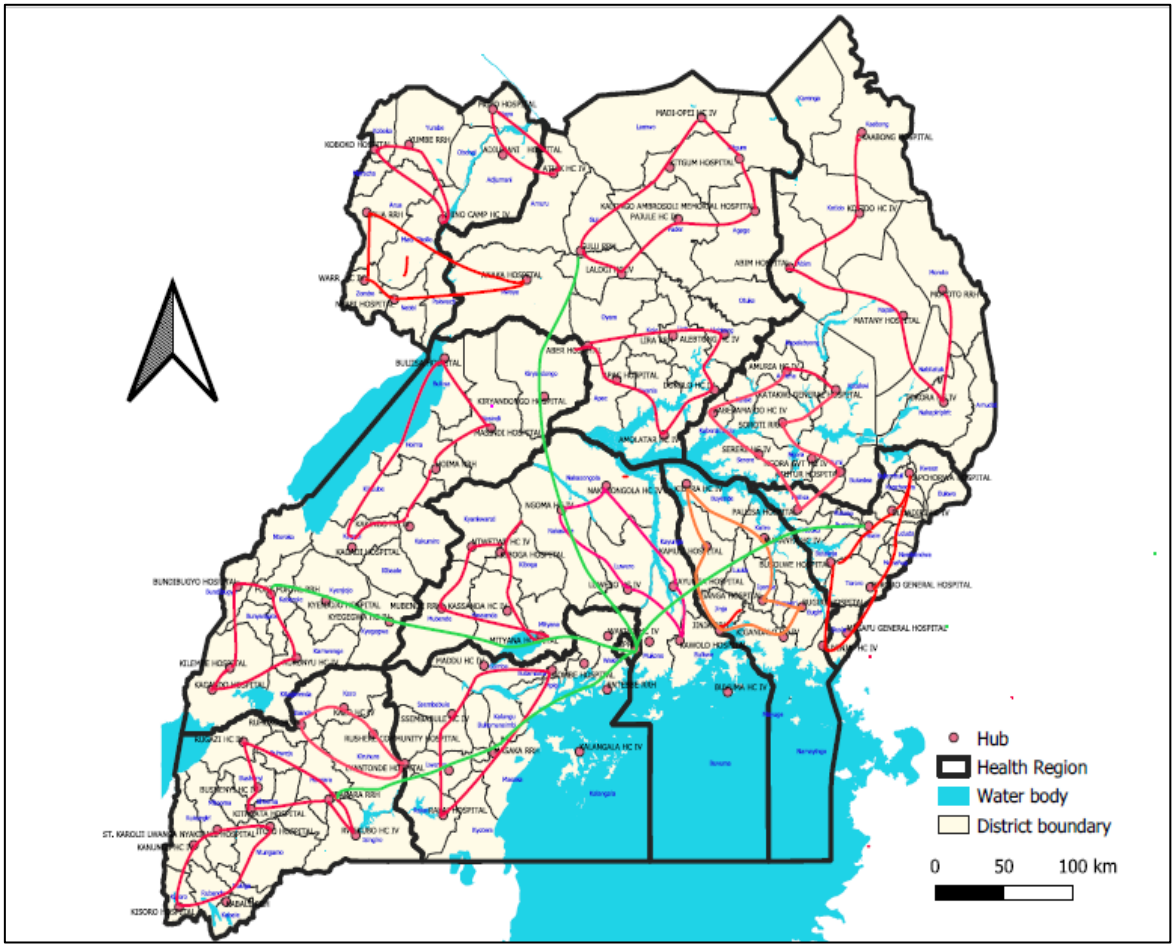


Fig 3: The National Health Lab hub and Sample Transport Network revised to include trunk vehicles, where no Posta services are available.

2.2.2 Animal Health

Animal health laboratory services in Uganda are coordinated by the department of animal health under the directorate of animal resources in the ministry of Agriculture Animal Industry and Fisheries (MAAIF). Under MAAIF, there are Regional Animal Disease Diagnostics and Epidemiology centres (RADDECs) that are set up to offer referral services to districts.

The national animal disease diagnostic and epidemiology centre (NADDEC) constitutes the national reference laboratory for animal health and directly coordinates operations of 14 district veterinary laboratories and 8 regional Veterinary Laboratories (Mbarara, Arua, Gulu, Mbale, Masaka, Lira, Moroto and Fort Portal). In addition to these, there are academia and research laboratories that provide back-up services to the NADDEC laboratories e.g. central diagnostic lab at COVAB and National Livestock Resources Research Institute (NaLIRRI).

The National Agricultural Research Act 2005 of Uganda established the National Agricultural Research System (NARS) which mandates NaLIRRI as the public agricultural research institute responsible for research and related services in Livestock Health, Nutrition, Breeding, Socio-economics, Marketing and Apiculture.

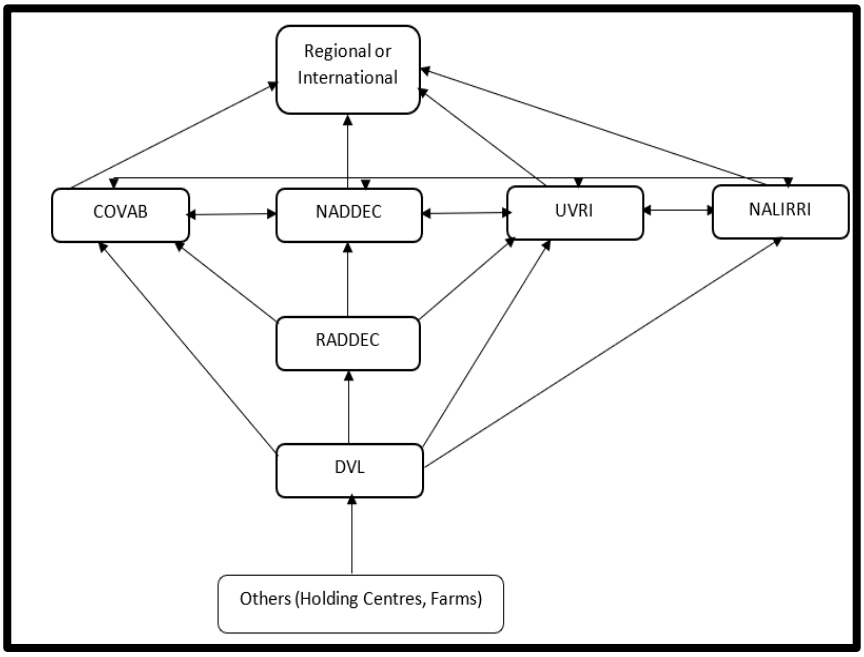


Fig 4: National Animal Health Network

2.2.3 Wildlife Animal Health

Uganda wildlife authority (UWA) under the Ministry of Tourism Wildlife and Antiquities is a statutory semi- automated body established in 1996 by an act of parliament (Uganda Wildlife Act Cap 200 of the laws of Uganda 2019) with a legal mandate to ensure sustainable management of Wildlife resources both inside and outside protected areas, coordinate, monitor, supervise activities related to wildlife management including translocations, re-introductions and re-enforcement of Wildlife laws.

The laboratory at Queen Elizabeth National Park is a biosafety level 2 and serves as the Referral Laboratory for UWA. There are 3 biosafety level 1 laboratories each at the Murchison Falls National Park, Bwindi Impenetrable National Park and Kidepo Valley National Park. Consequently, the UWA tier of Laboratories refers all testing that cannot be performed in its BSL 1 and BSL 2 to NADDEC, UVRI, COVAB or other International laboratories.

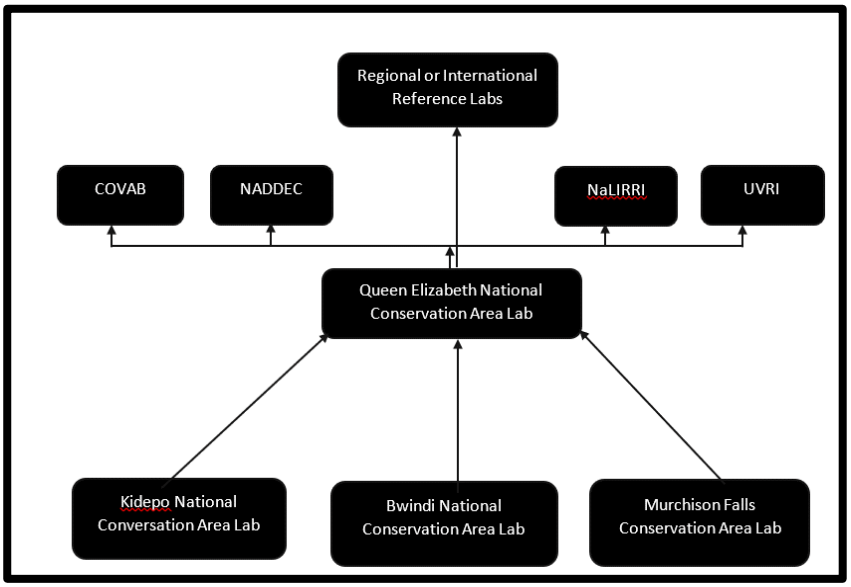


Fig 5: Schematic drawing showing network of UWA laboratories.

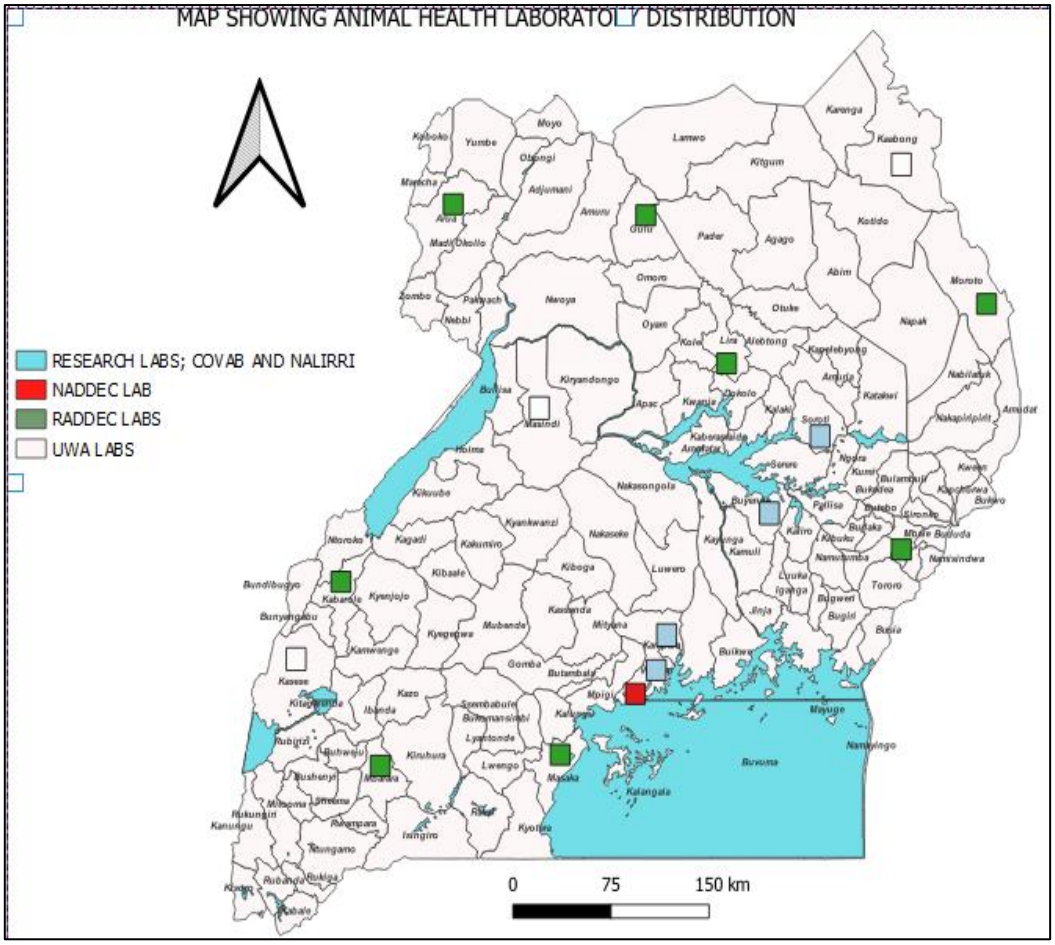


Fig 6: Map showing Animal Health laboratory distribution and RADDECs

2.2.4 Plant health

These laboratory services are coordinated by the department of crop husbandry under the directorate of crop resources in the ministry of Agriculture Animal Industry and Fisheries (MAAIF). The National Agricultural Research Organisation (NARO) has 16 Public Agricultural Research Institutes under its supervision, seven of these are known as National Agricultural Research Institutes (NARIs) and conduct research of national strategic importance. These laboratories include NACRRI, NASARRI, NAFORRI, NAFIRRI, NACORRI, NaLIRRI and National Agricultural Research Laboratories nine of which are Zonal Agricultural Research and Development Institutes (ZARDIs) conducting adaptive research in the nine agro-ecological zones of Uganda. The zones are Mbarara, Nabuin, Bulindi, Mukono, Kachwekano, Rwebitaba, Buginyanya, Abi and Ngetta.

2.2.5 Water and Environmental health

The Ministry of Water and Environment monitors the quality of water for public use through the Directorate of Water Resources Management, Department of Water Quality Management and a laboratory network at National and Regional level with District water officers to conduct Point of Care Testing (POCT). In addition, the National Water and Sewerage Corporation (NWSC); a government parastatal, has a network of laboratories at Central, Regional, Sub-regional and Area laboratories that support the monitoring of the quality of piped water distributed countrywide.

2.3 Laboratory Multi-sectoral Collaborations

In 2018 the Uganda national one health platform signed 'a one health strategic plan' that was critical to equip Uganda to prevent, detect and respond to zoonotic diseases, AMR and Biosecurity threats across sectors[14].

2.3.1 Integration of public health laboratory network under the one health approach

The one health strategic plan objective 3: - is to strengthen prevention, preparedness and response to zoonotic diseases and Biosecurity threats that dictate multi sectoral collaborations. The OHTWG shall establish a collaborative integration by strengthening the operations of the National Lab TWG, information flow and coordination through establishment of a national laboratory sub-committee. While the National Laboratory Guidelines for Preparedness and Response to PHEs are MOH documents, they describe the linkages between laboratory services across sectors and provide a platform for coordination at National, Regional and District levels.

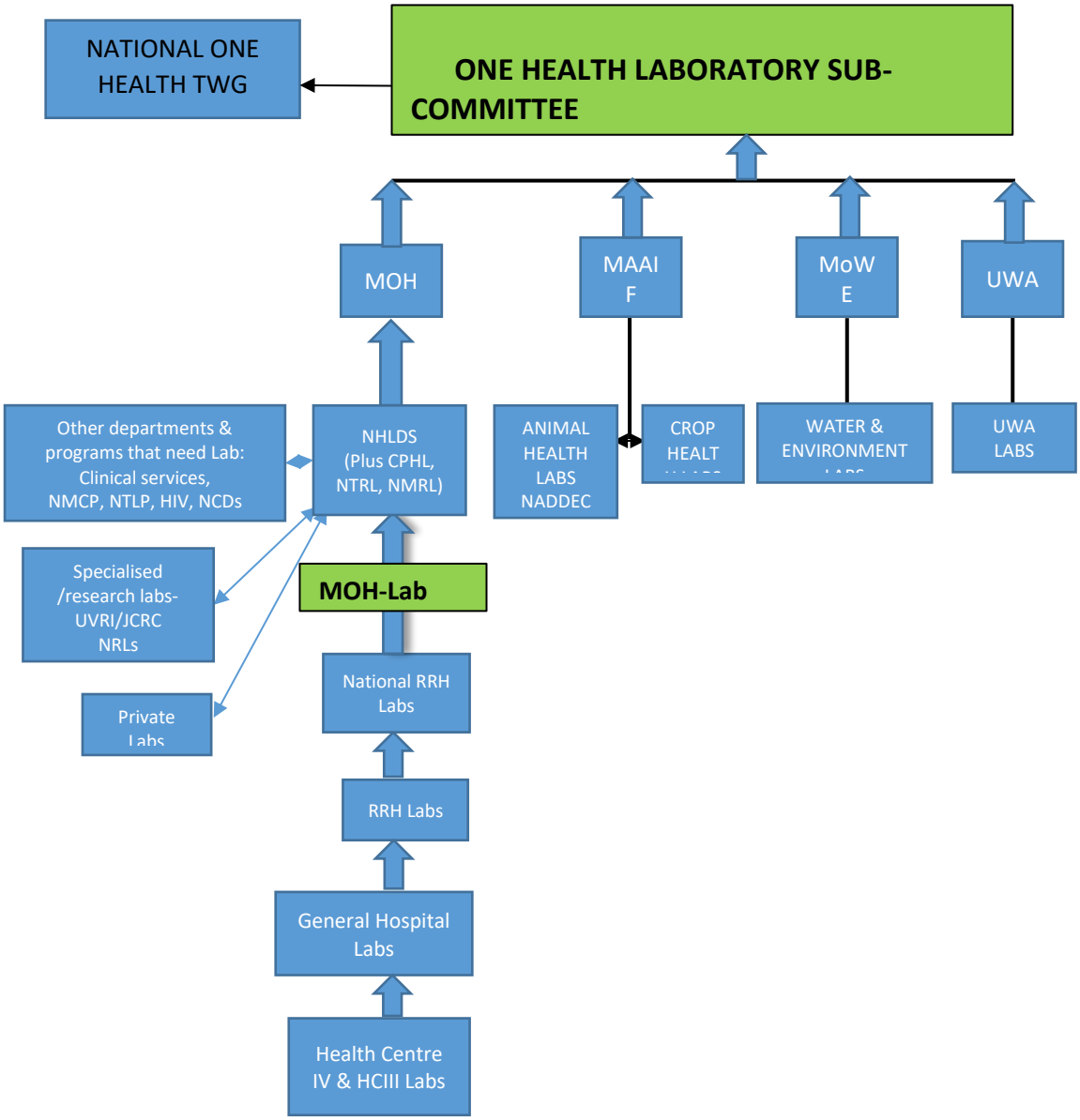


Fig 7: Interrelationships of the different Ministries, Departments and Agencies

[14] Uganda One Health Strategic Plan 2018-2022

As depicted in Fig 7, the laboratories with minimal capacity to perform basic tests can collect, package and refer samples to higher facilities with the capacity to analyse them.

2.4 Roles and responsibilities

2.4.1 Background

In both public and private health laboratories, there is an overlap of testing for clinical care and public health surveillance. While the focus of the clinical diagnostic testing is the individual patient care, public health laboratory testing concerns the population. Data generated from both clinical and public health testing contribute to robust surveillance systems. Noteworthy, in line with One Health, laboratories in the animal, plant, water and environmental sectors are all considered in describing these roles.

2.4.2 The functions of the laboratory department in preparedness and response:

The general functions for all laboratories are listed below.

- Provide stewardship in development of policy, standards and advocacy for public and private laboratory services; provide scientific and managerial leadership in implementation of public health policy; provide coordination and promotion of quality assurance programs for human, animal health and environment laboratories including training, consultation, certification and proficiency testing.
- Conduct capacity building (training and continuing education) for laboratory staff on laboratory technical (use of equipment, and appropriate and safe collection, storage and transportation of specimens) and managerial aspects.
- Ensure that testing meets specific needs of public health agencies. This includes timely laboratory confirmation of disease pathogens for surveillance, including epidemic alert, response and prevention, and monitoring microbiological safety of food and water.
- Ensure quality of all laboratory processes and procedures in line with national, regional and international standards.
- Develop and implement laboratory data and Information management systems, including mechanisms for sharing and use across the “One Health” sectors.
- Foster operational research and innovation in laboratory activities during preparedness and response to public health emergencies.

The table below describes the roles of laboratories and levels of work at different tiers of service delivery. The three categories of services are collection of samples, detection of epidemic prone diseases and reporting or notification.

Table 2: Roles of the laboratories in the network by level

Level of Service	1.0 Sample collection	2.0 Laboratory testing	3.0 Reporting or notification
Patients, animal owner, game warden	• Consent to sample collection and/or submit appropriate samples as requested by the laboratory staff.	• For self-testing, conduct tests following manufacturers' instructions or guidance given by the laboratory staff.	• Record results and report to the caregiver or health facility.
VHTs, Community Based Animal Health Workers	• Collect appropriate samples using appropriate supplies following standard operating procedures.	• Perform preliminary tests following the manufacturers' instructions and/or Standard Operating procedures.	• Record results and report to the caregiver or health facility.
HCII, Assistant Animal Husbandry Officers, Vet Officers, water officers	• Collect appropriate samples using appropriate supplies following standard operating procedures. • Package and Refer samples to the Testing laboratories for confirmation.	• Perform preliminary tests following the manufacturers' instructions and/or Standard Operating procedures.	• Record results and report to the caregiver or health facility.
First Contact Laboratory ***HC III, IV and General Hospital (District)***	• Plan for potential outbreaks (resource identification, capacity building) • Communicate collection policies, guidelines and procedures to providers • Collect appropriate samples following standard operating procedures. • Receive, verify, package and refer samples for confirmation to the reference laboratories. • Request additional specimen collection materials as needed	• Ensure all staff conducting tests are trained and deemed competent. • Perform laboratory tests for preliminary diagnosis following SOPs (e.g., microscopy, serology RDT) • Store representative slides, isolates from the outbreak as needed. • Observe changes in trends during routine analysis of laboratory results	• Record laboratory results • Provide results to clinical staff and patients • Report results to epidemiology offices • Report observed changes in trends during routine analysis of laboratory results • Use summary information in response to outbreaks.

	• Store specimens within approved conditions pending transportation or additional testing. • Direct additional collection materials as needed based on outbreak investigation		
National, Regional/Zonal Referral Laboratories (Some Reference laboratories may function as First Contact)	• Develop collection policies and procedures with national epidemiology office and national reference laboratories • Distribute specimen collection kits for special surveillance activities • Request additional specimen collection by laboratory or providers, as needed • Store specimens within approved conditions pending transport or additional studies	• Develop confirmation policies and procedures with national epidemiology office and national reference laboratories • Perform laboratory studies for confirmation as appropriate: culture, isolation, sero-group identification, antimicrobial susceptibility, serology • Store representative isolates from the outbreak as needed • Observe changes in trends during routine analysis of laboratory results	• Report results and summary data to national epidemiology office • Report laboratory results from screening sentinel populations at target sites
Specialised or Research or [15]Reference Laboratories	• Receive & accession samples from the referring laboratories.	• Perform confirmatory or specialised tests as appropriate	• Report laboratory results to appropriate epidemiology offices • Use summary information in response to outbreaks
International Reference Laboratories outside Uganda	• Request additional specimen collection by laboratory or providers, as needed • Direct additional collection as needed based on outbreak investigation	• Perform confirmatory tests & additional laboratory studies not available in country as appropriate	• Report laboratory results to appropriate epidemiology offices • Use summary information in response to outbreaks

[15] Reference laboratories are designated as such for example UVRI for virology; NTRL for Tuberculosis; CPHL for microbiology.

2.5 Mandates of the reference Laboratories

The national health laboratory policy section 4.1.3 to 4.1.5 provides policy statements for the roles of public health laboratory networks in disease detection and confirmation. This policy takes cognizance of Priority Zoonotic Diseases (PZDs) hence collaborative efforts with One Health sectors: human, animal and plant health; water and environment including wildlife and climate change.

2.5.1 National Health Laboratory and Diagnostic Services.

National Health Laboratory and Diagnostic Services (NHLDS) is a department in the Ministry of Health with mandate of overall stewardship, governance, and coordination of health laboratory services. It provides a platform for coordination of disease investigation, detection and confirmation, and antimicrobial resistance surveillance.

The department provides reference testing services for clinical virology including HIV viral load (VL), Early Infant Diagnosis (EID) and Hepatitis B viral load testing. The HIV Early Infant Diagnosis (EID) and Viral Load (VL) laboratories are internationally accredited to ISO 15189-2012 Standards through South African National Accreditation System (SANAS), and listed by the World Health Organisation (WHO) as a prequalification (PQ) laboratory for molecular HIV and HPV NAT diagnostics.

The department coordinates the National Sample Transport System (hub network) which connects more than 3,000 health facilities to move logistics, samples and results. This includes connecting reference and referral laboratories to the general laboratories. These laboratories are also inter-linked by the Laboratory Information Management System (LIMS) to share real time laboratory processes, test results, logistics status.

Core functions of the NHLDS

The following are core functions for the NHLDS

- Routine, reference, and specialised testing to confirm aetiology of health events
- Disease diagnosis, prevention, control, and surveillance
- Emergency response to public health threats
- Food safety monitoring
- Development of laboratory policy, guidelines, and standards
- Public health related operational research

The reference laboratories that constitute the NHLDS include:

1. **National Tuberculosis Reference Laboratory**: for detection and confirmation of tuberculosis, drug susceptibility testing of tuberculosis and isolation of drug resistant strains of tuberculosis. The Lab also provides technical training, operational research and EQA proficiency testing for laboratories within the network.
2. **National Microbiology Reference Laboratory**: supports disease confirmation for bacterial, fungal, parasitic pathogens, AMR surveillance, supports Microbiology Laboratory network, disease outbreak response, food safety, validation of diagnostics and diagnosis of infections due to rare infections or done using rare diagnostic testing.

3. **Central Public Health Laboratories**: Reference testing for HIV, Hepatitis B, Sickle cell disease, Public Health Laboratory, Malaria reference laboratory, Cancer/Pathology Reference laboratory.

2.5.2 Uganda Virus Research Institute

Uganda Virus Research Institute (UVRI) is an autonomous institution charged with the responsibility of conducting health research pertaining to human infections and disease processes associated with or linked to viral aetiology and providing capacity building to target beneficiaries.

The institute houses several national and international reference and specialised testing laboratories. In reference to the priority zoonotic pathogens, the department of Arbovirology Emerging and Re-Emerging Diseases at UVRI serves as a national and international reference centre for vector-borne and zoonotic viral infectious diseases.

Some activities of the UVRI include:

- Conducting field and laboratory research of vector-borne viral infections, their arthropod vectors, and zoonotic diseases;
- Developing and maintaining effective surveillance for vector-borne viral infections and their arthropod vectors;
- Defining disease aetiology, ecology, and pathogenesis for disease diagnosis, surveillance, prevention, and control;
- Provide diagnostic reference and epidemiological investigations for these priority diseases.
- Functions as a World Health Organisation Collaborating Centre for Reference and Research on Arboviruses and is the:
    - Yellow Fever Africa regional reference laboratory;
    - National Influenza reference laboratory;
    - Plague national reference laboratory.

2.5.3 Uganda Blood Transfusion Services

The Uganda Blood Transfusion Service (UBTS) is an autonomous institution established through commissioning in January 2003 by a Board of Directors. It operates within the framework of the national health policy and the Health Sector Strategic Plan. A national policy on blood transfusion was developed to guide the implementation of blood safety activities. The UBTS is mandated to provide blood services, which include organising blood donation campaigns, storage, processing and distribution to all health facilities whether Government or private, country wide.

The objectives of the UBTS are to:

- Expand blood transfusion infrastructure;
- Increase the annual blood collection country demand;
- Operate an active nationwide quality assurance program that ensures blood safety;
- Promote appropriate clinical use of blood;
- Strengthen organisational capacity of UBTS for efficient and effective service delivery.

In addition to blood services, the UBTS functions include clinical and research, diagnostics and therapeutic services, and transplantation services. In processing blood, UBTS screens for HIV 1/2,

Hepatitis B & C, and Syphilis. UBTS has grown from a service of supplying blood in central Uganda within a radius of 100kms from Kampala in 1989 to a network of seven regional blood banks at Arua, Fort- Portal, Gulu, Kitovu, Mbale, Mbarara and Nakasero. In addition there are six blood collection centres in Hoima, Jinja, Kabale, Rukungiri, Lira and Soroti.

2.5.4 The National Drug Authority

The National Drug Quality Control Laboratory (NDQCL) is a reference laboratory established under the National Drug Authority Act (1993). It is a World Health Organisation (WHO) prequalified laboratory with international ISO 17025 accreditation. Its mandate is to conduct quality assessment through laboratory analysis of medicines (human and veterinary), medical devices, surgical instruments and public health products while subsequently reporting accurate and precise results in a timely manner. The laboratory service spreads from pre-market, post-shipment and post-market surveillance.

The NDQCL conducts tests on:

- All human medicines including herbal medicines
- Veterinary medicines like acaricides
- Medical devices such as male and female condoms, surgical sutures, latex examination gloves, syringes and needles, Rapid Diagnostic Tests, surgical face masks
- Insecticide treated mosquito nets
- Hand sanitizers (Liquids and gels)

2.5.5 The Uganda National Bureau of Standards Reference Laboratory

The Uganda National Bureau of Standards (UNBS) is a statutory body under the Ministry of Trade, Industry and Cooperatives established by the UNBS Act Cap 327 and became operational in 1989. It is governed by the National Standards Council and headed by the Executive Director who is responsible for the day-to-day operation of UNBS.

The mandate of UNBS is:

- Formulation and promotion of the use of standards;
- Enforcing standards in order to safeguard on public health and safety and the environment against dangerous sub-standard products;
- Ensuring fairness in trade and precision in industry through reliable measurement systems;
- Strengthening the economy of Uganda by assuring the quality of locally manufactured products to enhance the competitiveness of exports in regional and international markets.

2.5.6 Directorate of Government Analytical Laboratory

The Directorate of Government Analytical Laboratory (DGAL) is a reference laboratory for forensic and toxicological testing services and is within the Ministry of Internal Affairs. DGAL exists to provide a full range of general scientific analytical, forensic and advisory services that facilitate effective legal proceedings to dispense fair justice; safeguard people’s and environmental health and safety.

The Directorate has historically been the leading provider of independent scientific analytical and forensic services in Uganda. The laboratory boasts of trained chemists, material scientists, technicians and laboratory management, with over eighty (80) years of industry knowledge and expertise provided since the 1930s.

The services of DGAL are:

- Forensic analysis of exhibits and samples
- Forensic advisory services
- Bio-and chemical-monitoring of environment, food and water supply systems for detection and prevention of bio-and chemical attacks to ensure public safety and health
- Biological and chemical official control testing / monitoring for conformity to standards
- Statutory testing to assure environmental health and safety
- Quality verification to facilitate trade and non-tax revenue collection
- Expert opinion to aid administration of justice, law and order

2.5.7 Wild life, Plant, Water and Environmental Laboratories

These include a range of laboratories including Uganda Wild Life Authority (UWA) reference laboratory, National Animal Disease Diagnostics and Epidemiology Centre (NADDEC), and the National Water Quality Reference Laboratory.

The National Agricultural Research Organisations (NARO) has sixteen crop and animal research laboratories. These include;

1. Public Agricultural Research Institutes (PARIs) in Namulonge, Wakiso
2. National Crop Resources Research Institute (NaCCRI) in Namulonge, Wakiso
3. National Forestry Resources Research Institute (NaFORRI) in Namulonge, Wakiso
4. National Livestock Resources Research Institute (NALIRRI), in Namulonge, Wakiso
5. The National Coffee Resources Research Institute (NaCORRI) in Mukono
6. National Semi-Arid Resources Research Institute (NaSARRI) in Serere
7. National Fisheries Resources Research Institute (NaFIRRI) in Jinja
8. National Agricultural Research Laboratories, (NARL) in Kawanda, Wakiso

2.5.8 Other Laboratories

There are other important laboratories in specialised institutions for research and service delivery. These include the:

1. Uganda Heart Institute (UHI),
2. Uganda Cancer Institute (UCI),
3. Infectious Diseases Institute (IDI) Core Laboratory
4. Baylor Uganda Laboratory,
5. Joint Clinical Research Centre (JCRC)
6. Makerere University Walter Reed Project (MUWRP),
7. College of Veterinary Medicine and Biosecurity Laboratory (COVAB)

2.6 Coordination of laboratory surveillance, preparedness and response activities

The Public health emergency operations centre (PHEOC) at the Ministry of Health coordinates the laboratory surveillance, preparedness and response activities to public health emergencies through effective situational awareness systems linked to all districts, all One Health stakeholders, and the National Public Health Emergency Operations Centre (PHEOC). The PHEOC directly conducts operational and strategic coordination, resource acquisition, and information gathering, analysis, and sharing to relevant stakeholders i.e. MoH, MAAIF, MWE and the UWA, an agency under the Ministry of Tourism Wildlife and Antiquities.

During an outbreak preparedness and response, the PHEOC assembles TWGs to constitute the Incident management team (IMT). This IMT consists of pillars such as;

1. Coordination, planning, financing and monitoring
2. Development of preparedness and response work plans and M&E and costed work plans
3. Risk communication, community engagement and demographic information management
4. Surveillance, outbreaks investigations and calibration of public health and social measures
5. Point of entry, international travel and transport, and mass gatherings
6. Laboratories and diagnostics
7. Infection prevention and control and prevention of the health workforce
8. Case management, clinical operations and therapeutics
9. Operational support and logistics, and supply chains
10. Strengthening essential health services and systems
11. Vaccination
12. Research, innovation and evidence

In November 2016, the One Health Framework was formalised through signing of a Memorandum of Understanding between the three (3) line Ministries and one agency (UWA), leading to the establishment of the Uganda National One Health Platform. The coordination of laboratory services in Uganda is in the context of the approved One Health Governance structure as shown in figure 8 below.

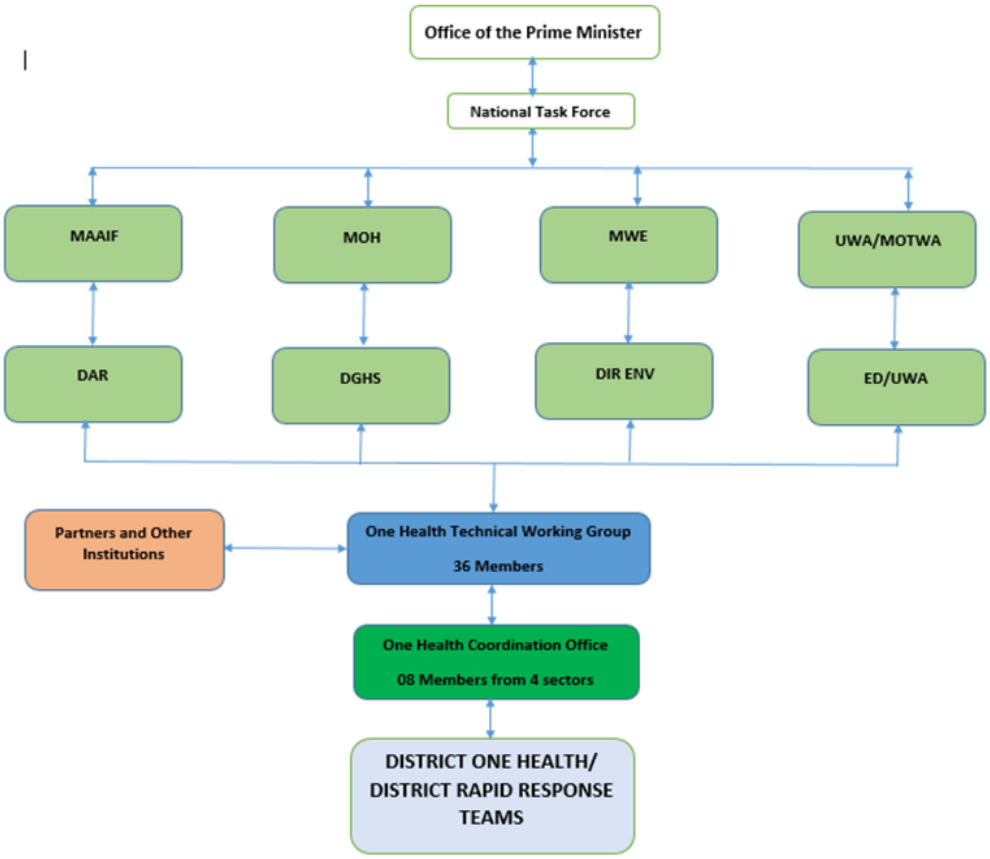


Fig 8: Approved One Health Governance Structure

2.6.1 National Laboratory Technical Working group (TWG)

The laboratory technical working group is the steering committee for policy development and implementation of laboratory surveillance, preparedness and response activities. It is constituted of representatives from the One Health line ministries.

The TWG will have designated focal persons from line ministries, departments, agencies, academia, implementing partners, development partners and private sector. The committee will be chaired by the chair of the laboratory TWG and work in collaboration with the National One Health Platform to strengthen its activities.

The TWG will analyse and provide input on the recommendations of the consultant team and staff to ensure the proposed updates to the code are usable and align with the policies in the Master Plan.

The group will serve as a sounding board for the laboratory technical arm to identify issues in draft documents and to brainstorm technical solutions.

2.6.2 Membership and roles

The oversight of public health laboratory activities in the country shall be carried in the context of the National One Health Policy at three primary levels, that is, the national, regional, and district levels.

The National level laboratory sub technical working groups include capacity building, coordination-policy and guidance, quality assurance, logistics, ICT, testing laboratories and POCT, data. These working groups contribute to timely coordination, management and response of prepared activities to public health threats.

Table 3: Laboratory Technical Working Group Steering committees

Steering Committee	Membership	Roles
Capacity building	The training officers from ministries subscribing to the One Health platform constitute the membership of the capacity building Laboratory Technical Working Group.	1. Identify training needs 2. Develop technical materials for trainings and post training capacity building activities such as mentorship, support supervision 3. Train national and regional trainers of trainers 4. Create and maintain the database for trainers 5. Train internal and external auditors 6. Create and maintain the database for internal and external auditors.
Coordination, policy and guidance	The Director for policy or delegates from Ministries subscribing to the One Health platform constitute the membership of the Coordination, policy and guidance laboratory technical working group.	1. Review existing guidelines, policies and other related legislative instruments in laboratory public health threats to identify gaps. 2. Develop policy agenda for consideration by line ministries 3. Draft policies in laboratory public health threats 4. Research and innovation
Quality assurance	The Quality Officers/ Managers from Ministries subscribing to the One Health platform constitute the membership of the quality assurance laboratory Technical Working Group.	1. Design quality management systems for the different laboratory 2. Develop and implement the programs for auditing 3. Develop the PT schemes for the laboratories 4. Develop SOPs for the laboratories 5. Coordinate internal quality assurance programs

		6. Develop and test new testing kits
Logistics	The Logistic Officers/ Managers from Ministries subscribing to the One Health platform constitute the membership of the logistic laboratory Technical Working Group.	1. Forecast laboratory supplies, reagents, equipment, PPEs, 2. Prepare and submit orders for laboratory supplies, reagents, equipment, PPEs 3. Service, calibrate and maintain laboratory equipment
Information Computer Technology, Data and M&E	The ICT Officers/ Managers from Ministries subscribing to the One Health platform constitute the membership of the ICT laboratory Technical Working Group. Monitoring and Evaluation professionals from the different sectors	1. Develop and maintain ICT systems/ infrastructure for reporting 2. Build capacity for national and regional teams on the use of developed ICT infrastructure 3. Input data into laboratory information management system 4. Release/dispatch test results
Testing laboratories and POCT	The Lab Managers from Ministries subscribing to the One Health platform constitute the membership of the testing laboratory Technical Working Group.	1. Build capacity for national and regional teams on the use of developed ICT infrastructure.

Membership and roles of the National Laboratory Technical Working Group Sub-Committees [16], [17], [18]

2.6.2 National Laboratory Pillar

The laboratory pillar provides strategic laboratory leadership in order to ensure timely diagnosis for appropriate decision making in terms of surveillance and case management. Membership is drawn from the TWG that consists of representations from One Health lining Ministries, Implementing Partners, Development Partners, private practitioners, and other stakeholders and partners. The

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[16] Labrador, N. foundland and. (2022). *Animal Health Laboratory - Fisheries, Forestry and Agriculture*. https://www.gov.nl.ca/ffa/programs-and-funding/programs/animals/health/health-lab/

[17] WHO AFR COVID 19 2021 SRP_Final_16042021.pdf

[18] Emergency Operations Centres and Incident Management Structure | Epidemic Intelligence Service | CDC

laboratory pillar is sub divided into national, subnational (regional) or district depending on the magnitude of the public health event.

Membership: The pillar is composed of technical laboratory teams from the One Health Laboratory Network, Development Partners, Implementing Partners, private sector, academic institutions and Reference Laboratories. These shall be appointed by the Chairperson of the National Laboratory Technical Working Group.

Roles and Responsibilities during preparedness

1. Coordinate all laboratory related activities in support of various public health threat preparedness, surveillance and response
2. Develop a preparedness and response plan including costed work plans and Monitoring and Evaluation plans for all Uganda's priority epidemic prone diseases
3. Establish and support collaboration with epidemiologists/surveillance officers
4. Define laboratory testing capabilities in-country and those referred internationally and share this information with all stakeholders
5. Coordinate laboratory logistics through development of supplies/reagents and equipment lists, their specifications and quantification based on the updated laboratory inventory.
6. Support the laboratory through advocacy with higher levels in accessing necessary infrastructure, equipment and supplies to collect, handle, test, store and ship specimens safely
7. Support the establishment and management of a national proficiency testing scheme for the laboratory network.
8. Support the development of standards and guidelines for collection, handling, testing, packaging,
9. Store and transport specimens including proper record for laboratory results for the laboratory Network.
10. Support the establishment of protocols and guidelines for Biosafety Biosecurity

Roles and Responsibilities during response

1. Conduct analysis of laboratory data at national level
2. Refine and implement the response plans
3. Conduct national laboratory pillar meetings
4. Liaise with epidemiologists/surveillance officers for effective response
5. Monitor laboratory stock and advise the national IMT accordingly
6. Support regions in epidemic response
7. Conduct support supervision with the aim of evaluating laboratory testing capabilities in-country and those referred internationally and share this information with all stakeholders
8. Distribute laboratory logistics in terms of supplies/reagents, PTs, and equipment to testing laboratories

9. Support the implementation of developed standards and guidelines for collection, handling, testing, packaging, storage and transportation of specimens including proper record for laboratory results for all testing laboratories
10. Conduct audits including biosafety, Quality management system with the aim of timely identification of areas of improvement, including timely error detection.
11. Prepare and submit reports to national incident management team

2.6.3 Regional Laboratory Pillar

Membership: The regional pillar is composed of technical laboratory teams from Regional Referral Hospitals, General Hospitals, Hubs and Regional Implementing Partners.

Roles and Responsibilities during the preparedness

1. Maintain an updated list of the laboratories that will perform required laboratory testing.
2. Provide information to all health facilities for appropriate specimen collection, packaging and shipment
3. Maintain and update an inventory of supplies, reagents and equipment from all the laboratories in the region
4. Ensure that laboratory confirmation procedures established at the national level are available and followed in the region and districts
5. Ensure that specimen collection, transport materials and laboratory diagnostic tests are available to enable timely detection of priority public health threats
6. Coordinate with health facilities and laboratory in collecting, safely packaging and reliably transporting the appropriate specimen for confirmation of suspected cases.
7. Receive results from the laboratory and promptly report them according to country procedures to all relevant stakeholders for public health action and patient clinical care.
8. Ensure that there is a proper record for laboratory results
9. Communicate with the reference laboratory and the National Laboratory Coordinators as appropriate.
10. Ensure that the laboratories have quality assurance programme to improve the reliability and reproducibility of laboratory results.
11. Ensure that support supervision and mentorship of the laboratories in the region takes place.

Roles and Responsibilities during the response

1. Attend national laboratory pillar meetings
2. Conduct analysis of laboratory data at regional level
3. Prepare and submit reports to the national laboratory pillar
4. Monitor laboratory stock of supplies and advise accordingly
5. Support districts in epidemic response
6. Conduct support supervision to district rapid response teams in terms of appropriate specimen collection, packaging and shipment
7. Prepare daily reports on stock levels for supplies, reagents and equipment from all the laboratories in the region and submit to stakeholders.

8. Ensure that disease confirmation procedures established at the national level are being adhered to by districts in the region
9. Ensure that there is timely specimen collection, referral, testing, and results return to enable timely detection of priority public health threats
10. Receive results from the laboratory and promptly report them, according to country procedures, to all that require them for public health action and patient clinical care.
11. Ensure that there is a proper record for laboratory results
12. Communicate with reference laboratory and National Laboratory Coordinators as appropriate
13. Ensure that the laboratories are participating in quality assurance programmes in order to improve the reliability and reproducibility of laboratory results
14. Conduct support supervision and offer mentorship to the laboratories in the region.

2.6.4 District laboratory Pillar

Pillar Membership: The pillar is composed of a technical laboratory team from General Hospital, Health Centre IV, and Health Centre III. These include; District Laboratory Focal Person/ supervisor, Hub coordinator and Health Facility Laboratory Managers.

Roles and Responsibilities during the preparedness

1. In liaison with the hub coordinator, establish or strengthen routine communication between identified laboratories that send and receive specimens at all levels
2. Prepare district laboratory procurement plans and provide technical support in procurement of laboratory supplies, and equipment and monitor their distribution and utilisation as informed by the laboratory inventory.
3. Ensure that laboratory staff are trained on SOPs for sample collection, transportation, confirmation of public health threats/conditions and results reporting.
4. Ensure the laboratories have quality assurance programmes in order to improve the reliability and reproducibility of laboratory results.
5. Coordinate and provide mentorship to the hub laboratories through support supervision.
6. Ensure implementation of Laboratory Quality Management Systems in all laboratories within the district.

Roles and Responsibilities during the response

1. Attend regional IMT meetings
2. Prepare and submit daily reports to the regional laboratory pillar
3. Prepare and manage duty rosters for laboratory staffs trained and competent in sample collection, transportation, confirmation of public health threats/conditions and results reporting.
4. Ensure that the laboratories actively participate in the quality assurance programme to improve the reliability and reproducibility of laboratory results.
5. Implement support supervision and mentor testing laboratories within the district including the POE laboratories.

6. Implement Laboratory Quality Management Systems in all testing laboratories within the district.

3.0 LABORATORY PROCESSES IN PREPAREDNESS AND RESPONSE

The Laboratory sector shall be prepared and ensure there is capacity in all facets of the laboratory to support pre-alert, alert, outbreak control and recovery phases. It is also key to have strategies in place for preparedness/peace time, at a time of individual cases, small clusters of disease and widespread disease. The key components include sample management, testing and archival, results management, Quality assurance, Biosafety & biosecurity and Personnel.

The Laboratories shall be well equipped to conduct laboratory-based surveillance and should as well fulfil requirements to allow for efficient and quality laboratory services. The preparedness phase shall be utilised to strengthen laboratory capacity using the available national approved strategies like SLIPTA/SLMTA, strengthening of Laboratories towards accreditation using respective ISO standards, complying to IHR using the GHSA, NAPHS & IDSR v3 among others.

During an outbreak the terrain of service delivery changes considerably and the laboratory shall be in position to support response outbreaks in addition to sustaining services for patient care and management. The number of specimens a laboratory receives may vary and at times, the number may even exceed the capacity of the laboratories to test and provide results.

3.1 Development of Laboratory Preparedness and Response plans, work plans and costed work plans

The National Laboratory Technical working group **MUST** develop a laboratory preparedness and response plan for each of the priority epidemic prone diseases and for all the immediately notifiable diseases.

The preparedness and response plans should include strategic objectives and activities in the following key areas: -

1. Development of Policies, guidelines and SOPs for the overall management of the disease
2. Description of Human resource capacity needs including training and deployment of government staff, recruitment and maintenance of surge teams and risk allowance and remunerations of staff
3. Strengthening sample collection, packaging and referral from lower facilities including from POEs
4. Strengthening testing capacity including Preliminary (POCTs) and confirmatory testing at centralised and regional laboratories; including plan for deployment of Mobile Laboratories
5. Strengthening data sharing and information management across sectors

6. Description of quality assurance at all tiers of laboratory services including internal quality control, External quality control, spot checks and supportive supervision in liaison with the AHPC.
7. Strengthening management of laboratory logistics for sample collection, packaging and transportation, Laboratory testing, data and information management, and Personal protective equipment, among others.
8. Biosafety, Biosecurity and other considerations - training of personnel, biosafety and biosecurity supplies, laboratory facilities and safety requirements as well as sample safety and security during transportation, testing and archival.

3.2 Indicator-based and event-based surveillance

Integrated Disease Surveillance (IDS) which constitutes event-based surveillance (EBS) and indicator-based surveillance (IBS) is aimed at collecting health data for multiple diseases using standardised tools, to support Early Warning Alert and Response (EWAR) systems. EBS is a rapid capture of information about events that are of potential risk to public health. Information is initially captured as a rumour or signal with potential of becoming an alert after verification. All alerts may not necessarily proceed to the event stage. As such alerts need to be triaged and verified before response initiation (refer to IDSR 3rd Edition.)

IBS is the regular, systematic, identification, collection, monitoring, analysis and interpretation of structured data, such as indicators produced by a number of well identified, mostly health-based formal sources. Types of IBS include; facility-based surveillance, case-based surveillance, sentinel surveillance, syndromic surveillance, **laboratory-based surveillance**, disease-specific surveillance and community-based surveillance.

3.3 Laboratory based Surveillance

Consistent sample analyses and utilisation of laboratory data is key in the early detection of public health emergencies and provides a model of monitoring infectious disease trends. The laboratory should ensure that all suspected cases have appropriate samples collected for both routine & outbreak investigation. Laboratory confirmation of disease detection, or conditions or events under surveillance is essential in order to:

- Accurately confirm the diagnosis in an individual patient, and
- Verify the cause (aetiology) of a suspected outbreak.

Laboratory based surveillance is essential in monitoring disease trends over time and useful for signalling the start of regular seasonal outbreaks of endemic diseases using alert and epidemic thresholds. “Laboratory-based” surveillance relies on the collection of information about diseases that have been identified by laboratory testing of ill or suspected persons.

3.4 Priority diseases requiring laboratory confirmation

The priority diseases that are the leading causes of illness, death and disability among human populations, are categorized into three groups: i) epidemic-prone diseases; ii)diseases targeted for

eradication or elimination, and iii) other diseases of public health importance as shown in the IDSR guideline.

3.4.1 Identification and notification of an alert in the laboratory

Routine laboratory processes include sample collection, sample testing and results management for clinical diagnosis, outbreak confirmation and monitoring prognosis. The laboratory product is a result of an identified pathogen causing disease in the patient.

When the laboratory identifies a pathogen of a prioritised disease of public health importance, the laboratory staff should notify the Laboratory Manager who then notifies the surveillance focal person of the facility, who in-turn reports the case in the DHIS2 or e-IDSR system and notifies the District Epidemic Preparedness and Response Committee (DEPRC); a committee of the District Disaster Management Committee (DDMC).

This DEPRC then sends a district rapid response team of which the Laboratory Response teams are part. The Rapid Response Teams (RRT) supports the facility to investigate the alert to its logical conclusion

3.4.2 Investigating an alert

Alerts are identified at facility level when there is an increase in test positivity rate and or a single immediately notifiable case, identified at the testing laboratory.

From the community, a rumour is sent to the DHT and the DSFP notifies the DEPRC who in–turn sends to the DRRT to verify.

Community and Health facility Alert investigations

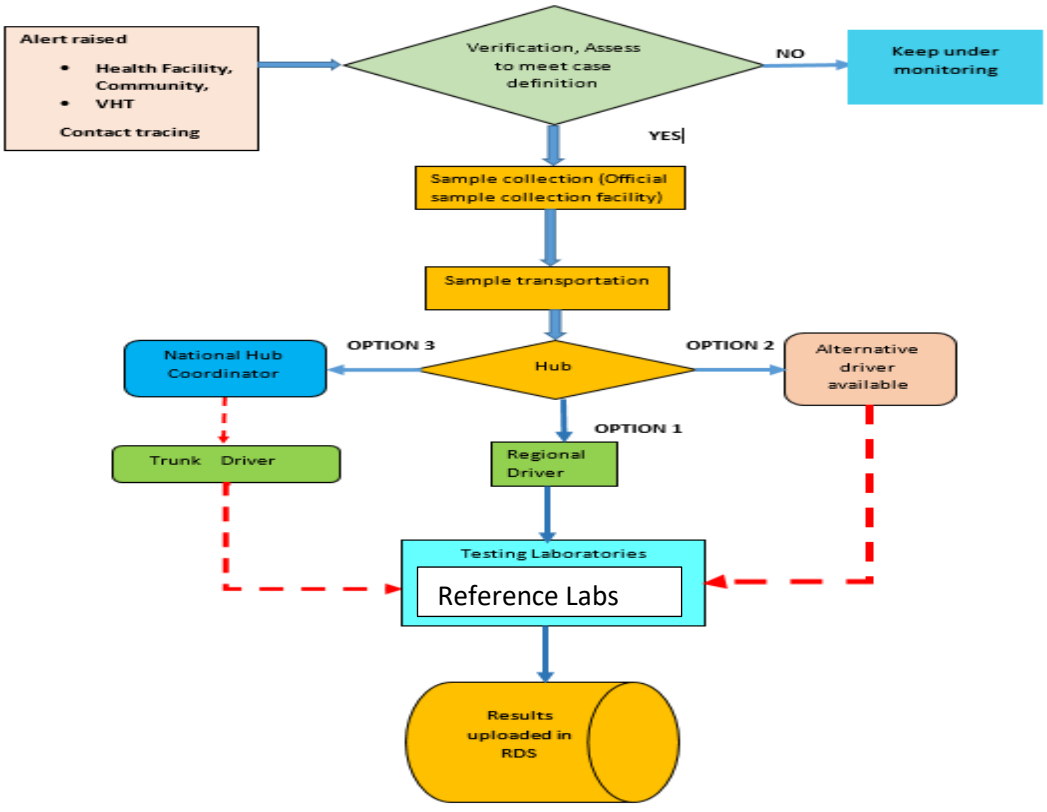
- All laboratory personnel participating in alert investigations should have all the necessary training on the SOPs of sample collection, packaging, transportation and testing, data and records management, Basic biosafety and biosecurity and Quality control for the suspected disease pathogen.
- The laboratory teams should ensure that all supplies needed are obtained prior to setting out for field investigations. Supplies inventory must be up to date and maintained at the district stores for outbreak investigations and these should be within their dates of expiry.
- When there is need for Laboratory confirmation in the community; the laboratory team collects the samples, safely packages and transports them to the nearest hub for testing or referral for confirmatory testing. In the event that Point of Care Testing (POCT) is available, a rapid test is done and the balance of sample/fresh sample (where applicable) is collected, packaged and referred for confirmatory testing. All waste generated in the field must be packaged, considered infectious and transported to the lab/hub with appropriate waste disposal facilities.
- At Health facility level samples are collected for preliminary testing if POCTs of priority epidemic prone diseases are available. The samples shall then be packed and referred for confirmatory testing at the reference laboratories.

3.4.3 Sample collection packaging and referral

- The choice of samples is dependent on the test to be performed. Reference testing laboratories should develop and distribute SOPs for sample management, packaging and referral. The SOP should include disease or condition, sample type, sample collection materials, and sample packaging materials. It should also include the procedure for sample collection, packaging and referral.
- The reference testing laboratories should conduct training for the laboratory staff involved in all sample collection.
- Laboratory specimens with suspected high consequence pathogens should not be manipulated in laboratories with no appropriate Biosafety and biosecurity measures. Only specimens deemed safe for that laboratory's biosafety level shall be manipulated at that laboratory.
- All specimens shall be accompanied by completed laboratory request forms or Laboratory investigation forms or case investigation forms.
- Laboratory specimens shall be well labelled with patient name, gender, age, date and time of collection and a unique laboratory identifier or lab number.

3.4.4 Where to send specimens for laboratory testing

Specimens shall be referred only to those reference laboratories with the capacity to conduct the tests required by the Rapid response team.



National Sample transport flexible for each response

Communication with the reference laboratories and hubs prior to sample collection is key.

The table 4: Showing the list of laboratories, tests done and turn-around-time (TAT)

S/N	Reference Laboratory	Type of test	TAT
1	CPHL - NMRL	**Bacterial, Fungal and Parasitic Infections** 1. MALDI TOF mass spectrometry • Bacteriology/Mycology 2. Culture for bacterial and fungal pathogens from: • Blood • stool, • urine • body fluid aspirates • pus • Sputum • Urethral and vaginal swabs etc 3. Provide evidence of outbreak suspected pathogens by analysing environmental samples: • Water • soil, • food, • vomitus etc 4. Antimicrobial susceptibility Testing by disc diffusion and MIC for: • Fungal isolates • Bacterial isolates 5. Detection of Antimicrobial resistance (AMR) of pathogens 6. Bacterial and Mycological pathogen identification (Conventional) 7. Black water fever (Malaria) 8. Modified Acid-fast stain for intestinal parasites:	2- 5 days

		• Cryptosporidium sp, • Isospora sp, • Microsporidium sp 9. Intestinal Parasites microscopic investigation for causes of • Schistosomiasis • Teaniasis etc 10. Blood Parasites Microscopic investigations for causes of: • Babesiosis • Malaria • Trypanasomiasis • Microfilaria. 11. Food poisoning investigation for pathogens causing: • Botulism • Listeriosis • Yersiniosis • enterotoxigenic Staphylococcus aureus food poisoning • Toxigenic Escherichia coli food poisoning • Salmonellosis • Bacillus cereus food poisoning etc 12. Watery diarrheal diseases investigation for causes of: • Cholera • Giardiasis 13. Bloody diarrheal diseases investigation causes • Shigella species (Shigellosis)	

		• Campylobacter species (Campylobacteriosis) • Salmonella Typhi & Para-typhi (Typhoid fever) • Entamoeba histolytica (Amoebiasis) • Entero-invasive Escherichia coli (bloody diarrhoea) • Gastrointestinal anthracis (bloody diarrhoea) • Shiga toxin producing Escherichia coli O157:H7 (bloody diarrhoea) etc. 14. Haemolytic uremic syndrome investigation for • Shiga toxin producing Escherichia coli O157:H7	
	CPHL - Central Emergency Response & Surveillance Laboratory (CERSL) and the CPHL Rapid Response Mobile Laboratories	**Molecular Testing** **1. Filoviruses** Ebola Virus Marburg Virus **2. Arboviruses** Yellow Fever Virus Rift Valley Fever Crimean Congo Haemorrhagic Fever Dengue Chikungunya West Nile virus Zika 3. **Viral Viral Respiratory syndromes** SARS-CoV-2 *4.* Environmental/Wastewater Based Surveillance for epidemic prone pathogens **ELISA test Panel:** • CCHF • Dengue • Ebola • Zika • Lassa	Within 24 hours 72 hours 1-2 days
2	CPHL – Genomics Laboratory	**Genomic Sequencing** ***1. Filoviruses***	2 -5 days

		▪ Ebola Virus ▪ Marburg Virus ***2. Arboviruses*** ▪ Dengue ▪ Chikungunya ▪ Zika ▪ Yellow Fever Virus ▪ West Nile virus ▪ Rift Valley Fever ▪ Crimean Congo Haemorrhagic Fever ***3. Viral Respiratory Infections*** ▪ SARS-CoV-2 ▪ Influenza A and B ▪ Respiratory syncytial virus (RSV) ▪ Rhino Virus ▪ Adenovirus **Metagenomics** ***Diseases of Unknown Aetiologies***	
4	CPHL – Other reference laboratories	1. Sickle cell lab, 2. Malaria research lab, 3. Nutrition lab, 4. Hepatitis Viral load, HIV viral load, 5. HIV-EID for children born to positive mothers 6. National Equipment calibration reference laboratory (NECRL)	3 days
5	UVRI	**Arboviruses** 1. Dengue NS1 2. Chikungunya (IgM and IgG) 3. Zika (IgM and IgG) 4. Yellow Fever Virus 5. West Nile virus 6. Onyong-nyong Virus 7. Bunyamwera Virus **Viral Respiratory syndromes** 1. SARS-CoV-2 2. Corona Virus OC43/HKU/NL63, 229 3. MERS-CoV-2 4. Influenza A (sub types H1, H1pdm09, H3, H5, H7) 5. Influenza B (B/Victoria and B/Yamagata) 6. Respiratory syncytial virus (RSV) 7. Rhino Virus 8. Human Metapneumovirus A and B 9. Adenovirus	2 days

		10. Enterovirus 11. Parainfluenza 1/2/3/4 12. Bocavirus 13. Mycobacteria pnuemoniae 14. Human parechovirus **Viral Haemorrhagic Fever (VHFs)** 1. Ebola Virus 2. Marburg Virus 3. Hantavirus 4. Haemorrhagic fever with renal syndrome 5. Crimean Congo Haemorrhagic Fever 6. Sosuga virus 7. Rift Valley Fever 8. Yellow fever **Other viruses** 1. Hepatitis A virus 2. Hepatitis E 3. HIV 4. Rabies **Tests done at UVRI Arua Station** 1. Anthrax 2. Plague 3. African Tick bite fever (rickettsial) 4. Brucellosis **UVRI Genomics Centre (Pathogen Sequencing)** 1. Inactivated Viral Haemorrhagic Fever Viruses. (Ebola viruses, Bundibungyo, Zaire and Sudan strains, Marburg virus, Rift Valley Fever virus, Crimean Congo Haemorrhagic Fever (CCHF) virus, Sosuga virus, etc. 2. HIV 3. Hepatitis 4. Other Arboviruses 5. Respiratory Viruses (Coronaviruses, Influenza, etc) 6. Immunizable diseases pathogens 7. Pathogen discovery - Known emerging and divergent pathogenic viruses: Rhabdoviridae (Le Dantec virus), Flaviviridae (Dengue virus), Tick-borne viruses in the family of Phenuiviridae e.g., Munguba phlebovirus, Mukawa phlebovirus, Dugbe	2-7 days

		Orthonairovirus, Picornaviridae e.g., Enterovirus C, Togaviridae e.g Madariaga virus, Hepatitis E virus, Echovirus, Enterovirus D68 virus. - Diseases of Unknown Aetiologies: novel viruses: picobirnavirus, Reoviruses, divergent bunyaviruses. - Environmental surveillance: COVID-19, Enterovirus C, Enterovirus B, Enterovirus D, Parechovirus A, Measles morbillivirus, Rotavirus C.	
6	UVRI – EPI Laboratory	Measles Rubella Mumps Polio	2 -5 days
7	NTRL	Tuberculosis	1 day
8	UBTS	Blood borne pathogens (Hepatitis, Syphilis, HIV)	1 day
9	NADDEC	Anthrax, Rabies, Trypanosomiasis, Brucellosis, Mycobacterium bovis, RVF, CBPP, PPR, FMD, Black quarter, ASF, Capripox, Avian Influenza, Newcastle Disease, Lumpy skin disease, CCHF	1 - 5 days
10	STD reference lab	HIV, Syphilis, Gonorrhoea	1 day
11	DGAL (National Forensic Referral Laboratory)	**Chemicals** **Naturally occurring toxins** 1. Mycotoxins (aflatoxin and ochratoxin) 2. Marine biotoxins 3. Cyanogenic glycosides 4. Toxins occurring in poisonous mushrooms **Persistent organic pollutants (POPs)** 1. Dioxins 2. Polychlorinated biphenyls (PCBs) 3. PFAS 4. PFOS 5. Hydrocarbons **Pesticide Residues** 1. Organophosphorous 2. Pyrethroids 3. Organochlorinated pesticides 4. Organonitrogens 5. Dithiocarbamates **Heavy metals** 1. Lead	5 days

		2. Cadmium 3. Mercury 4. Elemental analysis **Drugs of abuse** **Toxicological screening** `	

The Lab TWG should maintain an updated list of the laboratories that have the capacity to perform the required laboratory testing and have it widely circulated to all facility staff.

3.4.5 Transportation of infectious material

All laboratory specimens shall be packaged as per the classification of dangerous goods class 6 “toxic and infectious materials”, sub section 6.2 “infectious materials”. They should then be labelled as Category A- humans and Animals or Category B - Biological substances based on risk of exposure.

Packaging and shipping of infectious material must follow the International Air Transport Association (IATA) guidelines. According to IATA, diagnostic material is any human or animal material including, but not limited to; excreta, secreta, blood and its components, tissue fluids being shipped for the purpose of diagnosis but excluding live infected animals.

Triple packaging of infectious material is required. The primary container containing the specimen (e.g., freeze dried/slab culture) is surrounded by an absorbent material and packed into a water tight, leak proof secondary container. The secondary container is then packed in a tertiary water tight and leak proof container. The shipment should contain UN approved labels. The sender is responsible for: arranging with receiver and carrier, and notifying receiver. The carrier is responsible for preparing shipping documentation, and notifying the sender about packaging and transportation route, delays (e.g., in custom) and eventual receipt. The receiver is responsible for obtaining import papers, acknowledging receipt to the sender.

3.5 Laboratory testing

- The laboratories should ensure they have capacity to test for priority diseases as indicated in IDSR 3.
- Laboratory testing for diseases of public health emergencies should use approved testing algorithms for all tests and platforms.
- All facilities should follow the test menu for sample collection, testing and referral.
- Facilities at all levels should ensure they have appropriate biosafety and biosecurity levels to allow for testing of the respective samples.
- See list of tests for priority diseases tests in Annex 2 and corresponding testing platforms:

Minimum requirements for testing Platforms;

- **HC III to General hospital facilities:** Should have capacity to conduct preliminary tests for selected pathogens.

- **RRH and Reference or specialised facilities:** Should have capacity to conduct confirmatory tests for selected priority pathogens. Only National Reference laboratory results shall be used to declare an outbreak. Reference laboratories should take lead to prepare laboratory preparedness and response plans for all diseases confirmed in their laboratories, train personnel on sample management and testing capabilities. They shall prepare EQA in accordance to ISO 17043:2010 and ensure peripheral laboratories staff participate and are also assessed for competency.
- Reference laboratories shall conduct genomic sequencing for the pathogens identified at their facilities and where possible, expand capacity for sequencing to other back up laboratories.

Mobile testing laboratories during response

Mobile Laboratories are a fully-fledged laboratory with appropriate equipment and personnel designed for rapid deployment in areas far away from the reference laboratories to support real time confirmation of cases. There are two main models that exist for mobile laboratories. In the first model, the laboratory equipment and consumables are boxed, transported and unpacked into a tent or simple building. In the second, the laboratory is built into a shipping container or lorry that can be driven to the outbreak. Mobile laboratories are equipped and validated in advance to perform diagnostic testing of different biological agents and are designed to operate as independently as possible. Ideally, these mobile laboratories have reliable power and water supplies but often they can be run from generators or in the short term from vehicle batteries.

Deployment of Mobile Laboratories

1. Upon declaration of an outbreak, with a surge in cases, the Incident management team can approve a deployment of a mobile Laboratory to enhance rapid case confirmation.
2. The Director General/designee directs in writing the head of lab services and chair of the lab pillar to deploy the mobile laboratory.
3. Pre-deployment activities are triggered by selected requirements (Deployment letter from Director General MoH, Human resource, Training, Supplies, Deployment site assessment-closure of gaps identified in the assessment, Infrastructure, Waste management)
4. Quality assurance including validation of test methods, Internal Quality control (IQC) and inter-laboratory comparisons (ILAC) will be conducted with support from the National reference laboratory.
5. With satisfactory recommendation (s) from the National reference laboratory and IMT (laboratory pillar), the designated mobile Laboratory commences testing as per approved reference (s) or standard operating procedures.

Note: Withdrawal of the mobile laboratory will be guided by the technical teams, IMT and MoH. The Director General will provide approval to this effect.

3.6 Result management

Results for confirmation of an outbreak shall follow the incident management command systems and the National Disaster preparedness plan communication channels.

Managing positive results of epidemic prone diseases

Results obtained from reference laboratories shall be discussed at the National One Health Laboratory Technical Working Group and the line Commissioner communicates to the line Ministry. It is the line Ministry that then communicates to the President for declaration of the outbreak.

Subsequent results for patient management can be sent through the PHEOC and IMT directly to the requesting clinicians

Managing Negative results

Results shall be sent to the PHEOC and disseminated to the District Management Team for dissemination to the clinicians

3.7 Archival of specimens or isolates and retrieval of samples or isolates

All specimens or isolates shall be stored according to the National bio-banking guidelines.

1. All infectious disease specimens are a national resource for use in research investigations towards a better understanding and for the development of diagnostic tools. Every effort shall be made to archive specimens of epidemic prone disease outbreaks.
2. The procedure for archiving of specimens shall include proper documentation on the samples, timeliness for archival, indexing, procedure for retrieval in cases of retesting, access to the archive, maintenance and monitoring of proper storage conditions.
3. Research work on archived samples require the approval of the Ministry of Health, Uganda Ethical Review Board and Institutional Committees
4. Retrieval of such samples shall follow all clearance letters submitted to the National Laboratory Technical Working Group who will then authorise the laboratory manager of the biorepository laboratories to retrieve the samples

3.8 Laboratory Logistics

The Laboratory Technical Working Group should set up logistics requirements and quantifications to support outbreaks preparedness and response based on previous experience and scientific data obtained from report reviews.

The tool kits distributed per region shall be based on previous risk assessment done country wide for the epidemic prone disease prevalence.

The quantifications should then be given to the National Medical Stores (NMS) or any other store to procure and distribute to the recommended respective regional nodes for prepositioning.

Replenishment of these logistics shall be based on use and expiry of the supplies. At regional nodes the supplies near expiry can be exchanged with the regional referral hospital supplies with longer expiry.

During response, all supplies shall be requested from the regional nodes and replenishment shall be through the National Medical Stores (NMS) or agreed stores.

Redistribution to other districts shall require a letter of authorisation from the DHO of the district with supplies and a request letter from the DHO of the district requesting for supplies.

3.8.1 Physical structure

The construction of laboratory facilities requires standard designs that facilitate function, protect laboratory workers and provide barriers to ensure the safety of people outside the laboratory. *Refer to National Laboratory Infrastructure guidelines.*

3.8.2 Equipment requirement

The NPHLN should adopt a list of minimum laboratory equipment for the different levels as per the National Laboratory Standard test menu. A list of supplies for laboratory participation in outbreak investigations is provided in Annex 3. Laboratory equipment shall be assessed on a regular basis to ensure maintenance, availability, and quality.

Laboratories are encouraged to mobilise resources to adequately support laboratory capacity for confirmation of causative agents of priority infectious diseases. This ensures the ability to deal with emergencies and to deliver quality surveillance activities. The WHO/AFRO will support the procurement of reagents for network laboratories, from established WHO accredited laboratories for confirmation of epidemic-causing infectious diseases and for External Quality Assessment (EQA) scheme.

Funds shall be sourced for needed essential reagents and supplies identified for surveillance of diarrhoeal diseases, bacterial meningitis, plague and other essential laboratory-based surveillance activities. The requirements of each laboratory will vary according to its level and related activities. The Head of national laboratory services at the MoH will submit annually laboratory needs (at all levels), including the required budget for training, maintenance, replacement of laboratory equipment, reagents, and culture media.

Prepositioning, reallocation, distribution, requesting, issuing and stock management for essential laboratory supplies is critical for routine testing.

3.9 Quality Assurance and quality control

We should ensure capacity for laboratories to provide timely and quality laboratory test results of all outbreak samples. This shall be from sample collection, analysis up to result dispatch at all health service provision levels. Laboratory staff participating in outbreak preparedness and response activities shall be trained and deemed competent on all aspects of preparedness and response.

All laboratories supporting in the analysis of outbreak samples should fulfil the following requirements:

- All testing laboratories shall be registered and with a valid medical laboratory licence from the respective licensing body.
- All testing laboratories shall have a management team with responsibilities and interrelationships described in an organizational Structure.
- The Quality manager or officer shall be a qualified technical staff with defined responsibilities of establishing, implementing and maintaining a quality management system.
- Laboratory Management shall describe and document how it is committed to supporting the implementation of preparedness and response activities.
- Laboratory Management shall establish, document, implement and maintain a quality management system and continually improve its effectiveness.

3.9.1 Regulatory Inspections

- The Ministry of Health through its relevant Agencies, Departments and Officers, may perform regulatory inspections of any testing laboratory.
- Inspecting Agencies/Officers may include, but not be limited to UNHLDS, UVRI, AHPC, Uganda Police, Public Health Laboratory Incident Commander, the Deputy Incident Commander and other identifiable officers of the Ministry of Health.
- Regulatory inspections may or may not be communicated in advance.
  Officer(s) conducting a regulatory inspection shall formally identify themselves individually or through an official letter endorsed by a relevant office.

3.10 Biosafety and Biosecurity Considerations

Biosafety and Biosecurity considerations are central before, during and after disease outbreaks. Adherence to biosafety and biosecurity measures protects human health from hazardous biological agents and enables a safe targeted response to disease to be conducted based on scientific evidence in order to limit the spread and consequences of infectious diseases.

Biosafety: The greatest worry for persons responding to an outbreak is the risk of acquiring the infections from the microbiological agents handled. The situation is further made worse when the aetiology of the agent in question is unknown. Overall, the laboratory personnel engaged in the rapid response team should adhere to the following;

- Be trained and deemed competent to implement biorisk management measures
- The teams shall be taken through the risk assessment process prior to deployment. Once deployed, the team should undertake a thorough risk assessment exercise to understand the likely hazards that they will face during the response activities and set suitable mitigation measures to counter these risks.

- The choice of PPE to use and set up of the facility including deployment of the teams shall be based on a thorough risk assessment. The PPE requirements may include but not limited to gloves, coats, gowns, shoe covers, boots, masks, respirators, face shields, safety glasses, or goggles
- In cases where there is little information known about the agent in question then the teams should apply maximum containment principles and deploy highly competent staff to handle any work in this area.
- Additionally, Laboratory personnel safety practices and techniques must be supplemented by recommended immunizations (Hepatitis B virus, yellow fever and so on), and appropriate facility design and features, safety equipment, and management practices.
- Safety equipment shall be deployed based a thorough risk assessment process these include biological safety cabinets (BSCs), centrifuges with caps, an enclosed container designed to prevent aerosols from being released during centrifugation.
- Waste generated from all the procedures shall be handled as per the risk assessment guidelines.

Biosecurity refers to the protection of microbial agents from loss, theft, diversion or intentional misuse. This is accomplished by limiting access to facilities, research materials and information. Laboratory bio-security activities shall be established with clear and consistent policies and guidance. Training and familiarisation concerning the objectives and requirements of laboratory biosecurity activities shall be ongoing. *Further details are available in the WHO Guideline Laboratory Biosecurity Guidance*[19]

The secure storage of specimens containing highly virulent biological agents is of prime importance, both during an outbreak and once it has been declared over, to prevent loss, intentional release, theft, misuse and proliferation of biological agents. The patient specimens and the associated information gathered during an outbreak are a highly valuable resource for further research. The following biosecurity measures should therefore be instituted:

- Access to specimen storage areas must be controlled and only authorised persons allowed
- It is preferable that positive specimens from outbreaks be kept at the regional repositories except for select agents of national importance that will be kept at national specialized repositories.
- Biosecurity risk assessments shall be carried out and reviewed regularly including storage risks.
- During and after outbreaks, graded security shall be set up for laboratory and storage facilities even if this requires that specimens are shipped to alternative storage sites.

[19] http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

- Specimen storage facilities will require adequate funding to ensure continued security and power supplies, and to prevent degradation of either specimens or the surrounding security.
- A competent regional and national focal point person shall be identified to coordinate specimen repository at respective levels.
- Freezers used to store the specimens need to be maintained, kept in secure rooms and connected to a reliable power supply with a back-up generator available.
- Inventories must be kept for all the specimens and these should also be stored securely.
- In addition to ensuring long-term specimen security and integrity, consideration shall be given to laboratory managers to ensure biosecurity standards are maintained.
- Personnel competency shall be regularly evaluated to assure their continued suitability
- Training and competency in biosecurity shall be conducted for all the response team members

3.11 Personnel and Laboratory Response Teams

All laboratories should have a contingency plan for surge capacity and redistribution of roles during outbreaks.

3.11.1 General personnel requirements

- All personnel involved in outbreak preparedness and response should have been trained and deemed competent in the areas of sample collection, packaging and referral, laboratory testing for both preliminary and confirmatory, logistics, BSBS, Quality assurance and data management.
- Personnel already employed in government service shall formerly be requested to join the rapid response team through their respective authorities.
- Where necessary government staff can be deployed in any region of the country depending on their competencies, and shall receive appropriate remuneration as per government standing orders.
- Surge staff shall be recruited as required in respect to the nature of the response. All the surge staff shall receive contracts, get initial training and deployment by the National Laboratory Pillar.
- A testing laboratory shall have at a minimum a focal person for preparedness and response, and depending on the magnitude of the outbreak other staff with required competencies shall be taken on.
- All personnel involved shall be registered and regulated by the respective competent authority e.g., Allied Health Professionals Council (AHPC).
- The National Public Health Laboratories (UNHLS, UWA, UVRI, NADDEC, NWQRL, NALIRRI, DGAL, DDA) should regularly conduct short-term courses, have mentorships, workshops and refresher training for laboratory personnel.
- Laboratory personnel, microbiologists or technologists from the National Public Health Laboratory may be selected to undergo training in new techniques or re-training in basic techniques as required at the Regional Reference Laboratory or other WHO collaborating centres. Such training programmes could be arranged by the NPHL using its own contacts or through WHO or other partner agencies.

3.11.2 Personnel Training and Competence

- A testing laboratory shall have testing personnel, a minimum of 2 staff trained in testing processes and procedures for priority diseases, including sample collection and referral.
- The Laboratory shall implement a documented in-house structured personnel training program in testing techniques for the priority diseases in question and related procedures and processes prior to commencement of testing. These include; laboratory techniques, LQMS, assigned work processes, applicable LIMS, Health and safety/BRM, professional ethics / integrity and confidentiality of clients' information.
- Staff involved in public health laboratory testing and processes shall demonstrate competence in the assigned managerial and technical tasks. Such competence shall be periodically re-assessed at a defined interval according to established criteria.

3.11.3 Target groups for training

The National Public Health Laboratory Network should have a systematic and regular method of assessing training needs and skills development of staff. The aim of the training needs assessment shall be to:

- Identify the skills and levels of proficiency required for specific laboratory activities at each level of the network
- Determine the current level of proficiency;
- Assess the gap (i.e., the skills deficiency) between these two criteria and thus determine the training needs.

3.11.4 Personnel/Staff management and welfare during response

- Laboratory personnel shall be monitored for health and well-being and should always stay vigilant to hazards and threats. Lab staff should report even minor illness and injuries early to their Team Leader.
- All laboratory personnel shall be tested basing on the risk assessment during the outbreak period for which they are supporting; however, it shall be conducted monthly, at the minimum.
- During preparedness, all laboratory personnel shall be tested periodically and shall receive appropriate vaccination.

3.11.5 Remuneration and Welfare of the rapid response team

- NRRT, RRRT and DRRT members drawn from Government facilities shall be remunerated as per Government of Uganda public service standard orders.
- The staff on short contracts shall be remunerated as per their cadre equivalent to the current standard pay for that level, as a minimum.
- Risk allowance shall be paid to both categories of staff as per public service standing orders for all public health emergencies that present threats to the life of responders upon contraction of the disease.

4.0 MONITORING, EVALUATION AND REPORTING FOR LABORATORY PREPAREDNESS AND RESPONSE

4.1 M&E System

A functional M&E system is key in effective tracking of progress of implementation of the guidelines and generation of quality data; for timely decision making to address gaps, inform improvements and prioritise actions. This monitoring and evaluation section provides guidance to monitor progress in implementation of the interventions laid out for the laboratory preparedness and response guidelines across the various levels i.e., the sample collection points, districts, regional hubs, testing laboratories and at national level. The M&E framework with detailed key performance indicators, data management and reporting processes, roles and responsibilities of the various stakeholders in the monitoring and evaluation process.

Modern information and communication technologies have the potential to significantly improve data-sharing even in the most remote areas of developing countries. Such technologies shall be available to the National Public Health Laboratory network member laboratories and each should have official accounts for access. The monitoring and evaluation process, supported by ICT, will aid in:

- Capturing and analysing essential laboratory data; maintaining and sharing the data in standardised formats.
- Developing regular exchanges of information and surveillance data with other laboratories within the country and with other countries.
- Supporting a national network capable of receipt, storage, retrieval and analysis of laboratory surveillance data.
- Facilitating regular reporting of laboratory-confirmed notifiable diseases.
- Enabling timely flow of information between different levels and different professional groups within the health system.
- Having an established means of communicating rapidly with national authorities in relation to potential public health emergencies.
- Providing collated data to inform policy and decision-making authorities.

4.2 Laboratory data use and management

Data shall be generated using standard source documents developed by the NHLDS and approved by DHI for use in the country. However, when need arises, the National Laboratory Pillar can develop data tools and present to the DHI for customisation.

Data registers are available and already standardised as HMIS tools but as need arises, the lab pillar can develop a register and submit to DHI for approval before use.

Daily, weekly, monthly and quarterly data analysis shall be done by the Laboratory Manager/ In-Charge and submitted through the routine reporting systems (Indicator based surveillance).

For case-based reporting and event-based reporting, the case data can be entered into the system (e-IDSR or other system approved by the DHI) for routine data and response data.

During response, the lab pillar shall establish specific indicators to be reported upon, and a data analysis plan be developed. This shall be rolled out during trainings of laboratory teams as part of capacity building in the response.

The M&E unit at CPHL working closely with the DHI shall ensure this response data is restricted and released only to authorised persons.

It is the Ministry of Health to make any public pronouncements as regards to confirmation, progress and end of outbreaks. The Laboratory Teams shall desist from releasing any information in their custody to the public to avoid causing panic.

Sharing of data with WHO

Preparedness and response data generated shall be kept at the MOH and communication with other partners including WHO is through authorised persons as delegated by the President.

Reporting of epidemic prone diseases by private health laboratories

Upon identification of a priority disease the laboratory is directed to report such cases to the DSFP and DLFP. Results of such cases shall then be reported through the appropriate reporting channels.

4.5 Indicator Matrix

Guiding performance measurement indicators for the laboratory pillar during preparedness and response are provided in the M&E matrix below.

Table 5: Monitoring and Evaluation Matrix

INDICATOR	DEFINITION	DISAGGREGATION	DATA SOURCE	FREQUENCY	RESPONSIBILITY
Strengthening sample collection, transportation and tracking and results return system					
1.1 Proportion of sample collection points with up-to-date guiding materials	**N:** Number of sample collection points with up-to-date guiding materials **D:** Number of sample collection points	By Type of sample collection point By Category (SOPs, Manuals, Registers and Reporting Forms)	**N:** Laboratory Capacity Checklist **D:** District Task Force Reports, RESTRACK	Monthly	District Laboratory Focal Person (DLFP), PHEOC
1.2 Proportion of districts/cities with laboratory tool kits for epidemic prone diseases	**N:** Number of districts with laboratory tool kits for epidemic prone diseases **D:** Total number of districts	By District/City	District Lab and Surveillance Sub-committee reports	Monthly	NHLDS, PHEOC
2.1 Number of samples referred for testing	**N:** Number of samples referred for testing	By District/City	**Paper Based:** HMIS Lab 005: Laboratory Specimen Referral Register; Referring Facility Specimen Referral Log **Electronic:** the electronic result dispatch system-RDS, ODK	Monitored daily, monthly at each referring facility	DLFP, NHLDS
2.2 Number of shipments dispatched	**N:** Number of shipments dispatched	By District, By Hub	electronic result dispatch system-RDS, ODK	Monitored monthly at each referring facility	DLFP, Hub Coordinator
2.3 Proportion of referred samples for which a result was returned	**N:** Number of referred samples for which a result was returned **D:** Total number of samples referred during the reporting period	By District, By Testing laboratory	**Electronic Based:** Electronic results dispatch system	Monitored monthly at each referring facility	DLFP, Testing Lab
2.4 Proportion of referred specimens for which a result was received within the specified target time	**N:** Number of referred specimens for which a test result was received within (24-72hrs)	By District, By Testing laboratory	Time sample is sent, is obtained from the electronic sample tracking system-eSTS; time result received is	Weekly, Monthly	DLFP, Testing Lab

	D: Total number of specimens referred for which a result was returned		obtained from the electronic sample dispatch system-eRDS)		
2.5 Proportion of shipments which were picked up by the transport service within 12 hours of collection	**N:** Number of referred shipments which were picked up by the transportation service within 12 hours of collection **D:** Total number of specimens picked up by the transportation service	By sample transportation method	**Paper Based:** HMIS Lab 005: Laboratory Specimen Referral Register; Referring Facility Specimen Referral Log or transport logs, Hub riders register	Monitored weekly, monthly at each referring facility	Hub Coordinator
2.6 Proportion of shipments that were delivered to the testing laboratory within 24 hours of collection	**N**: Number of shipments that were delivered to the testing lab within 24 hours of collection **D**: Total number of shipments transported during the reporting period	By referral laboratory, By Sample Collection Point, By sample transportation method	**Electronic:** RESTRACK system (Parcel bar codes)	Monitored weekly, monthly	Hub Coordinator
2.7 Proportion of sample that were delivered to the testing laboratory within 24 hours of collection	**N**: Number of samples that were delivered to the testing lab within 24 hours of collection **D**: Total number of samples transported during the reporting period	By referral laboratory, By Sample Collection Point, By sample transportation method	**Paper Based:** Chain of custody form or Specimen referral log (At the testing Lab)	Daily, Weekly, Monthly	Hub Coordinator, Testing Lab
2.8 Proportion of shipments that were reported to be lost or damaged in transit	**N**: Number of shipments that were reported to be lost or damaged in transit **D:** Total number of shipments	By referral laboratory, By Sample Collection Point, By sample transportation method	**Electronic:** RES-track system (Parcel bar codes)	Daily, Weekly, Monthly	Hub Coordinator, Testing Lab
2.9 Proportion of samples that were lost or damaged	**N**: Number of samples that were lost or damaged in transit **D:** Total number of samples sent	By referral laboratory, By Sample Collection Point, By sample transportation method	**Paper Based:** Chain of custody form or Specimen referral log	Daily, Weekly, Monthly	Hub Coordinator, Testing Lab
2.10 Proportion of samples received with incomplete or absent Lab investigation Forms (LIFs)	**N:** Total number of samples received with incomplete or absent Lab investigation Forms (LIFs) **D**: Total number of samples received	By referral laboratory, By Sample Collection Point	**Electronic:** RESTRACK system (Specimen bar codes)	Daily, Weekly, Monthly	DLFP, Hub Coordinator, Testing Lab

Testing capacity of Public Health Laboratories					
3.1 Number of active Public Health Laboratories conducting Testing for Epidemic Prone Diseases	Number of active Public Health Laboratories conducting Testing for Epidemic Prone Diseases	Level: Centralized, Decentralized, Category: Mobile/field based or facility based (PoEs, Health Facility)	NHLDS, Lab Sub-pillar	Monthly	**NHLDS**
3.2 Proportion of shipments that arrive at the referral laboratory within the specified transport time	**N:** Number of shipments that arrived at the referral laboratory within the specified transport time	If applicable, by individual courier or route	Transport logs	Monitored monthly at each referral laboratory	Hub Coordinator, Testing Laboratory
3.3 Proportion of referred samples tested at the referral laboratory	**N:** Number of referred samples tested at the referral laboratory **D:** Total number of samples received at the referral laboratory	Testing laboratory	Referral Laboratory Specimen Reception Log, laboratory investigation forms	Weekly Monthly	NHLDS, Testing Lab
3.4 Proportion of test results that were picked up by the transport service or transmitted electronically within the specified turn-around-time after generation of the test result	**N:** Number of test results that were generated for referred specimens that were picked up by the transportation service or electronically transmitted within the specified turn-around-time after generation of the test result **D:** Number of test results that were generated for referred specimens and returned to the referring sites	Testing laboratory	Referral Laboratory Specimen Reception Log and transport logs	Monitored monthly at each referral laboratory	Testing laboratory
3.5 Proportion of specimens that were rejected (Rejection rate)	**N:** Number of specimens that were rejected because of factors related to inadequate or improper transportation or packaging or documentation **D:** Number of specimens received	By reasons for rejection, referral site	Referral Laboratory Specimen Reception Log and transport logs	Monitored monthly at each referral laboratory	Testing Laboratory, NHLDS
3.6 Percentage (%) of positive, negative and invalid test results	**N:** Number of positive, negative and invalid **D:** Total number of tests conducted	Testing laboratory	Lab Testing Registers, Results Dispatch System	Weekly Monthly	NHLDS, Testing Lab

3.7 Percentage (%) of failed IQC results	**N:** Number of tests that failed IQC results **D:** Total number of tests conducted	Testing laboratory	IQC Report	Weekly Monthly	NHLDS, Testing Lab
OUTBREAK LOGISTICS MANAGEMENT					
4.1 Ratio of total no. of sample collection kits delivered against the projected, within specified period at national level.	**N:** Total number of sample collection kits delivered at the national stores **D**: Projected test kits within specified period at national level.	Sample collection kits, Weekly, monthly	Procurement plan	Weekly, Monthly	NHLDS
4.2 Ratio of number of tests available against projected number of tests within the reporting period	**N:** Total number of tests available at the national stores **D:** Total projected number of tests within the reporting period	Weekly, monthly	Procurement plan	Weekly, Monthly	NHLDS
4.3 No. of testing Laboratories that Stocked out in a specified period	Number of stock out days for tracer items supplies	Tracer Items	Facility stock status report	Weekly, Monthly	NHLDS
OUTBREAK EQUIPMENT MANAGEMENT					
5.1 Equipment down time	Number of days equipment breakdown before repair	Equipment platform, By testing site	Facility Report	Weekly, Monthly	NHLDS
5.2 Proportion of equipment with service contracts	Number of testing laboratories with service contracts	Equipment platform, By testing site	Facility Report, Service contract	Quarterly	NHLDS, Testing Labs
5.3 Proportion of equipment with up-to-date equipment book of life	**N:** Total number of equipment with up-to-date equipment book of life **D:** Total equipment in the testing laboratories	By testing Lab		Quarterly	NHLDS, Testing Labs
5.4 Proportion of laboratories with back-up services	**N:** Number of testing laboratories with back-up services **D:** Number of EPIDEMIC PRONE DISEASE testing laboratories	Equipment platform	Back-up services Agreement	Weekly	NHLDS, Testing Labs
OUTBREAK QUALITY ASSURANCE					
6.1 Turn-around-time within the testing lab from reception to upload of	Turn-around-time within the testing lab from reception to upload of results onto the results system	By Testing Laboratory	RDS, e-LIMS	Weekly	NHLDS, Testing Labs

results onto the results system					
6.2 Number of laboratories participating in on-site evaluation by an external body/agency	Number of laboratories participating in on-site evaluation by an external body/agency	By Testing Laboratory	EQA Reports	Monthly, Quarterly	NHLDS, Testing Labs
6.3 Number of laboratories participating in re-checking or re-testing in accordance with WHO recommendations	Number of laboratories participating in re-checking or re-testing in accordance with WHO recommendations	By Testing Laboratory	QA Reports	Monthly, Quarterly	NHLDS, Testing Labs
6.4 Proportion of laboratories participating and meeting 80% satisfactory EQA score in the WHO EQA (PT) scheme or its equivalent	**Numerator:** Number of laboratories participating in the WHO EQA (PT) scheme or equivalent meeting >=80% satisfactory EQA performance **Denominator:** Number of laboratories participating in the WHO EQA (PT) scheme or equivalent	By Testing Laboratory	EQA Reports	Monthly, Quarterly	NHLDS, Testing Labs
BIOSAFETY BIOSECURITY AND IPC PROGRAM					
7.1 Proportion of Public Health testing laboratories that register 80% and above BRM Score	**Numerator:** Number of Public health testing laboratories with a BRM score above 80% **Denominator:** Number public health testing laboratories	By Testing Laboratory	BRM Reports	Monthly, Quarterly	NHLDS, Testing Labs
7.2 Proportion of sample collection points that register 80% and above BRM Score	**Numerator:** Number of sample collection points with a BRM score above 80% **Denominator:** Number of sample collection points	By sample collection point	BRM Reports	Monthly, Quarterly	NHLDS, DLFP
7.3 Proportion of epidemic prone disease testing laboratories with an up-to-date pathogen inventory	**Numerator:** Number of EPIDEMIC PRONE DISEASE testing laboratories with an up-to-date pathogen inventory **Denominator:** Number of EPIDEMIC PRONE DISEASE testing laboratories	By Testing Laboratory	Pathogen Inventory Reports, Assessments	Monthly, Quarterly	NHLDS, Testing Labs

7.4 Proportion of laboratory staff scoring above 80% in BRM assessments	**Numerator:** Number of laboratory staff scoring above 80% in BRM assessments **Denominator:** Number of laboratory staff assessed in BRM assessments	By Testing Laboratory	BRM Assessments	Weekly, Monthly	NHLDS, Testing Labs
7.5 Proportion of laboratory health workers enrolled in the EPIDEMIC PRONE DISEASE health worker surveillance program	**Numerator:** Number of laboratory health workers enrolled in the EPIDEMIC PRONE DISEASE health worker surveillance program **Denominator:** Number of laboratory health workers supporting EPIDEMIC PRONE DISEASE response	By Lab, By Cadre	National Laboratory Training database (at National Laboratory Pillar)	Weekly, Monthly	NHLDS, Testing Labs, PHEOC
7.6 Proportion of EPIDEMIC PRONE DISEASE testing laboratories that score 90% in waste management	**Numerator:** Number of labs that score 90% in waste management **Denominator:** Number of EPIDEMIC PRONE DISEASE testing laboratories	By Lab	Waste Management Assessments, BRM	Weekly, Monthly	NHLDS, Testing Labs, PHEOC
7.7 Proportion of laboratory staff trained on EPIDEMIC PRONE DISEASE Laboratory Diagnostics	**Numerator:** No. of laboratory staff trained on EPIDEMIC PRONE DISEASE Laboratory Diagnostics **Denominator:** Total number of targeted laboratory staff	By District/City, By Level, By Cadre	Monthly	Weekly, Monthly	DLFP, NHLDS
7.8 Number of coordination meetings convened according to schedule	Number of coordination meetings convened according to schedule	By Pillar	Minute**s**	Weekly, Monthly	NHLDS
7.9 No. of staff available to meet required surge capacity	No. of staff available to meet required surge capacity	By Cadre	Surge staff report	Weekly, Monthly	NHLDS
11.2 Proportion of hubs utilising the sample tracking electronic system (RES-TRACK)	**Numerator:** Number of hubs and sample collection points utilising the sample tracking electronic system (RES-TRACK) **Denominator:** Total number of hubs and sample collection points	By Hub, District	Res-track	Weekly, Monthly	Hub Coordinator, NHLDS
11.3 Proportion of testing laboratories uploading	**Numerator:** Number of testing laboratories uploading results into the	By testing lab	eLIMS/RDS	Weekly, Monthly	NHLDS

results into the eLIMS within 48 hours of receipt of the sample	eLIMS within 48 hours of receipt of the sample **Denominator:** Total number of testing laboratories in the network				
11.4 Proportion of district/facility/PoE staff authorized to receive results for epidemic prone diseases able to access them using the results dispatch system	**Numerator:** Number of sample collection points with requisite electronic sample tracking tools **Denominator:** Total number of sample collection points	By District, By Regional Hub	eLIMS/RDS	Weekly, Monthly	DLFP, PHEOC NHLDS
M&E & REPORTING SYSTEM					
12.3 Proportion of facilities/laboratories submitting complete reports	**Numerator:** Number of laboratories submitting complete reports **Denominator:** Number of laboratories expected to submit reports	By Level (National, District, Testing Lab)	DQA Reports, ODK or available Information System	Weekly, Monthly	PHEOCS, NHLDS
12.4 Proportion of facilities/laboratories submitting reports timely	**Numerator:** Number of laboratories submitting complete reports **Denominator:** Number of laboratories submitting reports	By Level (National, District, Testing Lab)	DQA Reports, ODK or available Information System	Monthly	PHEOCS, NHLDS
12.5 Proportion of facilities/laboratories submitting accurate reports	**Numerator:** Number of laboratories submitting accurate reports **Denominator:** Number of laboratories submitting reports	By Level (National, District, Testing Lab)	DQA Reports, ODK or available Information System	Monthly	PHEOCS, NHLDS

5.0 RESOURCE MOBILISATION, COORDINATION AND ADVOCACY

Mobilisation of funds for the development and continuity of laboratory services for preparedness and response to public health emergencies will be the role of the Laboratory Pillar and the Incidence Management Team.

The Government line Ministries and District Local Governments shall, through funds from disaster preparedness and or other sources, support activities for the implementation of the guidelines, complemented by partner support.

6.0 Annexes

Annex 1 International and National Legal frameworks/policies Supporting Laboratory Service Delivery

i. **Agenda 2030 - Sustainable Development Goals:** These aim to achieve decent lives for all on a health planet by 2030. There is global recognition of the key role of health in achieving Sustainable Development Goal 3 (good health and well-being) and other related Goals 5 and 6.

ii. **East Africa Community (EAC) Vision (2050)**: Mandates partner states to make continued investments in health infrastructure systems as well as building capacities of health personnel. Laboratory detection capacities will be enhanced to ensure a healthy and productive sub region that is free from diseases and pandemics[20].

iii. **Global Health Security Agenda:** This is an effort by Nations, International Organisations and civil society to accelerate progress toward a world safe and secure from infectious disease threats through detection, assessment and reporting; to promote global health security as an international priority; and to spur progress towards full implementation of IHR (2005).

iv. **Guide for National Public Health Networking to strengthen integrated disease surveillance and response:** Is to strengthen District-level surveillance and response for priority diseases, to integrate surveillance with laboratory support, and to translate information generated from surveillance and laboratory data into specific public health actions.

v. **Integrated Disease Surveillance and Response (IDSR):** This is a WHO-AFRO regional strategy for strengthening capacity for laboratory detection and response to public health emergencies at community, Health Facility, District and National levels in an integrated manner to maximise resources.

vi. **International Health Regulations (2005)**: The purpose of the IHR 2005 is to provide guidance to countries on how to achieve core capacities on prevention, detection and response to public health emergencies while avoiding unnecessary disruption to international trade and travel.

vii. **Regional Strategy for Health Security and emergencies 2016:** The strategy contributes to the achievement of SDG3, emphasising the need to strengthen multisectoral collaboration for better prevention, preparedness and response to epidemics and other health emergencies.

viii. **Animal Diseases Act Chapter 38 laws of Uganda:** The act provides for the laboratory detection of animal diseases including zoonotic diseases.

ix. **Delivery of Veterinary Services policy (2002)**: This policy provides for laboratory disease detection including zoonotic and other emerging diseases.

x. **Health Sector Development Plan (2015/16-2019/20):** The HSDP goal is „To accelerate movement towards Universal Health Coverage (UHC) with essential health and related services needed for promotion of a healthy and productive life". HSDP indicates the need to strengthen laboratory services at all levels to provide basic, complementary, referral and specialist laboratory services. It emphasises that the laboratory quality management system

[20] East African Community, Vision 2050

should be well co-ordinated for the provision of quality and equitable services at all levels in the health laboratory network.

xi. **National Action Plan for Health Security (NAPHS) 2019-2023:** The five-year plan has 19 technical areas, of which National Laboratory Systems is among the major cost drivers. Development and implementation of the National Laboratory guidelines for Preparedness and Response of Public Health Emergences will greatly contribute to positive changes in the country's IHR Core capacity and health security scores.

xii. **National Health Policy II (2010-2020):** The goal of the National Health Policy II is "To attain a good standard of health for all people in Uganda in order to promote healthy and productive lives". The priority targets are: Build and strengthen capacity of health facilities to improve health service provision, including rehabilitation and equipping of these units; improvement of laboratory and diagnostic services, provision of trained personnel, drugs and other essential supplies, consistent with established standards[21].

xiii. **National Policy for Disaster Preparedness and Management 2011:** The implementation of these guidelines will be in accordance with the roles and responsibilities of various actors outlined in the National Policy for Disaster Preparedness and Management.

xiv. **Parish Development Model:** This is a guide to all the stakeholders in organizing and delivering public and private programme interventions for wealth creation at the Parish level as the lowest economic planning unit[22].

xv. **Plant Protection Act:** This is a guide to the country to designate laboratories and competent scientists as official identifiers of biological specimens.

xvi. **The National Environment Act 2019:** It provides for management of the environment through designation of analytical laboratories and reference laboratories for timely detection of public health emergencies in the environment[23].

xvii. **The Public Health Act (amendment 2022):** This is an act to strengthen detection during preparedness and response to public health emergencies.

xviii. **The Uganda National One Health Strategic Plan (2018-2022)**: This plan aims at promoting multi-sectoral and interdisciplinary application of knowledge and skills of medical, public health, veterinary and environmental experts by working together to address animal, human and environmental health challenges[24].

[21] National Health Policy, 2010- 2020

[22] Implementation Guidelines for PARISH DEVELOPMENT MODEL

[23] https://www.nema.go.ug/projects/national-environment-act-2019

[24] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7758849/

Annex 2: List of Tests for Priority Diseases

Suspected Disease	Type of Specimen	When to collect the specimen	Where to refer Specimen	Type of test(s)	Comments
Dysentery	Stool	On each suspected Case.	National Reference Lab	• Culture and sensitivity testing • Identification by chemical test (note that *S.dysenteriae* 1 is always catalase negative) • Agglutination with specific antisera*	For antibiotic sensitivity, test: Nalidixic Acid, ampicillin, ciprofloxacin, Cotrimoxazole, chloramphenicol an d tetracycline
Cholera		On each suspected case.	National Reference Lab	• Culture and sensitivity testing • Serotyping by specific antisera agglutination (polyvalent O1, Ogawa, Inaba) antisera anti *V. cholerae* 0139)	For antibiotic sensitivity, test: Erythromycin, tetracycline, Nalidixic Acid, Cotrimoxazole
Meningitis	CSF	On each suspected case (even during non-outbreak seasons)	District or Regional or National. Ref Lab.	• RDT (Latex agglutination) • Gram stain • Cytology on CSF	Send to Reference Lab for confirmation and antibiotic sensitivity
			National Reference Lab	• CSF culture and sensitivity testing	For antibiotic sensitivity, test: Oxacillin, Chloramphenicol, Cotrimoxazole, ceftriaxone
Plague	Serum	On each suspected Case	Designated National and/or Reference Laboratories	• RDT test • ELISA test	Send to national reference laboratory or to the regional laboratory.
	Bubo aspiration and/or Sputum	On 10 First cases	Designated National and or Reference Lab	• Culture from bubo or sputum	Regional or confirmatory and ATB sensitivity

TB	Sputum	On each suspected case	Designated National and/or reference lab	• Microscopy • Culture and sensitivity for sputum	ATB sensitivity testing
STD	Urethral pus Blood	On each suspected case	District, Regional, National	• Gram stain • Serology • Culture, Sensitivity	
Malaria	Thick blood smear	On the first 20 cases	Designated National and/or reference lab	• MGG stain	
VHF	Blood samples	On the first 10 cases	Designated regional/international reference laboratories	• ELISA/PCR	Send to regional or international reference laboratories
Respiratory syndromes (SARI, ILI, SARS, MERS, COVID)	Sputum, oro-pharyngeal, naso-pharyngeal swabs	On each suspected case	Designated district, regional, national lab	• RDT/PCR	Test RDT at site or send sample to designated testing lab.

Annex 3: Sample collection toolkit for selected Epidemic prone diseases

SN	TOOL KIT FOR EPIDEMIC PRONE CONDITIONS	
	DISEASES	**TOOL KIT CONTENTS**
1	Anthrax	Swabs, Gloves, EDTA, Cryovial, Plain top, A pair of gum boots, Request/Investigation forms, Biohazard bag, 2ml/ 5ml syringes, Sharps box, Triple packaging kit, N95 respirator, Shoe cover, Surgical gown, Ziplock bag
2	COVID-19	Nasal/Oral swab, Gloves, Surgical gown, Shoe cover, N95 respirator, Triple packaging kit, Ziplock bag, A pair of gum boots, Request/Investigation forms
3	Haemorrhagic fevers (Marburg, EVD, RVF, CCHF WNF, YF, Lassa)	Disposable coveralls, A pair of gum boots, N95 respirator, Hood, Shoe cover, Goggle/face shield, surgical/examination gloves, Jik (0.5& 0.05%), Plain vacutainer, Body bag, Biohazard bag Investigation form, Triple packaging kit, EDTA vacutainer, Sharps box, 2ml/ 5ml syringes, Ziplock bag
4	Plaque	N95 respirator, Examination gloves, Surgical gown, Gumboots, Sanitizer, EDTA, Syringes, Biohazard bag, Triple packaging kit
5	Rabies	Cryovial, A pair of forceps, surgical blade, Surgical blade handle, Biohazard bag, face shield/ goggles, normal saline, Triple packaging kit, Surgical gown, Gumboot, Examination gloves
6	Typhoid fever	Stool container, Tissue paper, Examination gloves, Surgical gown, face shield/ goggle, Biohazard bag, Triple packaging kit, 2ml/ 5ml syringes, Sharps box
7	Dengue Fever	EDTA vacutainer, Sharps box, 2ml/ 5ml syringes, Biohazard bag, Triple packaging kit, Surgical gown, Examination gloves, Ziplock bag, Sharps box
8	Malaria	Slides/EDTA vacutainer, Sharps box, Examination gloves Laboratory coat, Surgical mask
9	Acute Viral Hepatitis	Plain /EDTA vacutainers, Examination gloves, 2ml/ 5ml syringes, Sharps box, Biohazard bag, Surgical gown, Laboratory coat
10	Cholera	Stool container, Cary-blair transport media, Surgical gown, Examination gloves, Tissue paper, Biohazard bag
11	Diarrhoea with blood (Shigella)	Stool container, Buffered glycerol saline, Examination gloves, Biohazard bag, Tissue paper, Surgical mask
12	Bacterial Meningitis	Syringes, Examination gloves, Stool container, EDTA vacutainer, Plain vacutainer, Sodium citrate/Grey top, Sharps box, Biohazard bag
13	Acute Flaccid paralysis	Stool container, Triple packaging kit, Investigation form, Examination gloves, Biohazard bag, Tissue paper
14	Measles	2ml/ 5ml syringes, Sharps box, Surgical gown/ lab coat, Biohazard bag, Triple packaging kit, Investigation form