

Building Testing Capacity for **Epidemic-Prone Diseases**

Guidance to African Union Member States

April 2023

Contents

Acknowledgement	iii
Executive Summary	iv
Background	v
Purpose	v
List of priority epidemic-prone diseases	vi
Testing for Epidemic-Prone Diseases.....	1
Viral Haemorrhagic Fevers.....	2
Crimea-Congo Haemorrhagic Fever.....	2
Dengue.....	2
Ebola virus.....	3
Marburg virus	3
Lassa Fever.....	3
Rift Valley Fever Virus	3
Respiratory Infections.....	3
Watery Diarrhoea	4
Meningitis	4
Arboviruses	4
Yellow Fever.....	4
Chikungunya	5
Zika.....	5
Mpox	5
Poliovirus	5
Anthrax	5
Measles.....	5
Plague	5
Wastewater Surveillance	6
Testing for Disease Surveillance	6
Recommended Laboratory Capacity.....	7
Nucleic Acid Amplification Tests.....	8
Rapid antigen tests	8
Antibody-based tests.....	9
Culture	9
Genome sequencing	9
Laboratory systems strengthening for epidemic preparedness	10

Regulatory capacity	10
Diagnostic network optimization and community-based surveillance	10
Quality.....	11
Training	11
Supply chain.....	11
Data systems.....	12
Biosafety and biosecurity.....	12
Annex	13
Survey of Current Laboratory Capacity.....	13
Testing Capacity	13
Disease Surveillance.....	14
Integrated and Multiplex Testing Capacity	15
Epidemic preparedness gaps	15
References	16

Acknowledgement

The Africa Centres for Disease Control and Prevention (Africa CDC) acknowledges the enormous contribution received from its Partners during the development of this guidance for building testing capacity for epidemic-prone diseases.

In particular, the Africa CDC appreciates the technical inputs provided by the Members of the AFTCOR Laboratory Technical Working Group whose deliberations enriched the guidance to foster building testing capacity for epidemic-prone diseases.

In addition, the Africa CDC would like to recognize and acknowledges the individual listed here below for the review and inputs provided during the development of this guidance:

- Abebaw Kebede (Africa Centres for Disease Control and Prevention)
- Abimiku Alash'le (Institute of Human Virology, Nigeria)
- Andrew Auld (CDC/DDPHSIS/CGH/DGHT)
- Anne Von Gottberg (National Institute for Communicable Diseases, South Africa)
- Aytenev Ashenafi Eshete (Africa Centres for Disease Control and Prevention)
- Belinda Herring (WHO Regional office for Africa (WHO/AFRO)
- Collins Otieno (African Society for Laboratory Medicine)
- Fatim Cham-Jallow (The Global Fund)
- Gerald Mboowa (African Society for Laboratory Medicine)
- Jane Carter (Amref Health Africa)
- Jane Cunningham (World Health Organization)
- Juliet Bryant (The Global Fund)
- Kekeletso Kao (FIND)
- Neha Agarwal (PATH)
- Ndlovu Nqobile (African Society for Laboratory Medicine)
- Osborn Otieno (The Global Fund)
- Pascale Ondo (African Society for Laboratory Medicine)
- Raymond Kennedy (Clinton Health Access Initiative)
- Rosanna Peeling (London School of Hygiene & Tropical Medicine)
- Sofonias Kifle Tessema (Africa Centres for Disease Control and Prevention)
- Trevor Peter (Clinton Health Access Initiative)
- Vivianne Gomo (The Global Fund)
- Yenev Kebede Tebeje (Africa Centres for Disease Control and Prevention)

Executive Summary

The provision of health and other services in the African region is challenging due to protracted humanitarian emergencies, poverty, lack of political commitment, and fragile health systems. This has resulted in a number of retrograde health indicators, an increase in the burden of infectious diseases, and the emergence and re-emergence of high-risk pathogens. Over the last few decades, many outbreaks and epidemics have been reported across the region with the potential for local health and socioeconomic impact as well as international spread, including Yellow fever, Rift Valley fever, Mpox, measles, Crimean-Congo haemorrhagic fever, Dengue fever, Chikungunya fever, Ebola virus diseases, Marburg virus disease, Cholera, and COVID-19. Most of these outbreaks were not detected early due to the lack of real-time surveillance, lack of optimal functional laboratory networks, inadequate diagnostic testing capacity at both national and peripheral levels of healthcare, inadequate human and other resources, and lack of adequate technical and managerial capacities. Through its Africa Task Force for Novel Coronavirus (AFTCOR) Laboratory Technical Working Group, the Africa Centres for Disease Control and Prevention (Africa CDC) has developed guidance on “Building Testing Capacity for Epidemic-Prone Diseases”. The aim of this guidance is to enhance the surveillance and diagnostic capacity of African Union (AU) member states. The guidance provides the recommended testing approaches for surveillance and clinical diagnosis of epidemic-prone diseases, and details on the diagnostic technologies and laboratory capacity needed to conduct testing. Recommendations are provided on leveraging existing laboratory capacity to establish readiness to prevent, detect and respond to emerging and epidemic-prone infectious diseases, based on evidence and best practices for disease control.

This guideline is intended to be used as a common resource by AU member states and other stakeholders involved in formulating preparedness and responses to emerging and epidemic-prone infectious diseases, to enhance surveillance, and to strengthen laboratory diagnostic capacity based on national and regional priorities.

Background

Reports of disease outbreaks in Africa are becoming more common and unpredictable. Over the past decade, certain regions of Africa have experienced some of the largest recorded outbreaks of infectious diseases. In 2013–2016, the world’s largest Ebola virus disease outbreak occurred in West Africa and spread internationally (1). In 2015–2016, Angola and the Democratic Republic of the Congo (DRC) experienced a large outbreak of yellow fever, while Nigeria experienced a major Mpox epidemic. In 2017, the worst reported plague outbreak in Africa occurred in Madagascar (1), while in 2020 Africa and the world at large experienced a pandemic of COVID-19 (2). As of February 2023, a total of 12,409,100 COVID-19 cases and 256,698 deaths were reported by the 55 AU member states. From the beginning of 2023, 99 confirmed cases and 23 deaths from Mpox were reported from four endemic AU member states and 32,528 cases and 901 deaths from cholera were reported from 10 AU member states (2). Outbreaks of Dengue fever, Lassa fever and measles have also been reported, as well as increases in zoonotic disease transmission. Over the past decade, there has been a 63% increase in reported diseases transmitted from animals to humans in Africa (1).

The Africa CDC has identified an initial list of priority epidemic-prone diseases in Africa using a risk ranking and analysis tool to inform effective emergency preparedness and outreach response (2). For example, Ebola virus disease, cholera and COVID-19 scored highest for disease severity, risk and epidemic potential, as well as need for preparedness in terms of vaccine availability and medical or non-medical countermeasures (1). The list of priority diseases is provided below. This prioritization helps to determine which infectious diseases to target for epidemic preparedness and response actions.

Improved epidemic preparedness requires adequate diagnostic capacity for early detection and management of priority diseases. Limited access to diagnostics has been a bottleneck for the early detection of priority diseases in Africa. Diagnostic capacity has often focused on diseases such as HIV, TB, malaria and more recently COVID-19, while in many settings diagnostic capacity for diseases such as dengue fever, ebola virus disease and rift valley fever is limited. However, laboratories and health systems established for diseases, such as COVID-19, TB, HIV, and malaria can be used for the detection of other priority diseases of epidemic potential, thereby expanding the range of pathogen detection capacity in AU member states and reducing cost. The integration of testing and the effective use of existing diagnostic platforms and laboratory infrastructure were demonstrated with SARS-CoV-2 testing during the COVID-19 pandemic. In addition, some tests are available in multiplex format. Multiplex testing enables the detection of multiple pathogens in a single sample and is valuable for both surveillance and clinical management.

Establishing improved diagnostic capacity for priority diseases of epidemic potential through integrated testing within existing laboratory capacity and with multiplex testing will improve epidemic preparedness, aid early detection and response, and help prevent outbreaks from becoming pandemics.

Purpose

The purpose of the document is to guide AU member states in the establishment of diagnostic capacity for diseases with epidemic potential. This guidance provides a list of priority epidemic-prone diseases in African countries and the recommended testing approaches both for surveillance and clinical management

purposes. The guidance provides a list of the diagnostic technologies and laboratory capacity needed for these diseases, and recommendations on the laboratory capacity needed to establish diagnostic readiness for outbreaks. It also highlights opportunities for integrated testing and multiplex testing. National testing strategies, diagnostic technologies selected, and the approach to implementation should be developed based on country context, local epidemiological conditions, and available resources.

List of priority epidemic-prone diseases

The International Health Regulations published in 2005 identifies disease mapping and health risk and resource prioritization as one of the core capabilities of public health emergency preparedness and response. Effective preparedness and swift responses to outbreaks is the goal of the Africa Centres for Disease Control and Prevention.

Through a multidisciplinary consultation forum, Africa CDC in collaboration with the European Centre for Disease Prevention and Control (ECDC), applied a ranking methodology to prioritize epidemic-prone diseases and public health events occurring in Africa that require rapid and effective responses (2,3). **The diseases priority setting is in the broader context of public health emergency preparedness and response planning.**

The list of priority diseases is below:

- COVID-19
- Cholera
- Ebola virus disease
- Measles
- Meningitis
- Polio
- Anthrax
- Yellow fever
- Lassa fever
- Marburg virus disease
- Rabies
- Rift Valley fever (RVF)
- Chikungunya
- Crimean-Congo haemorrhagic fever (CCHF)
- Dengue fever
- Mpox
- Plague
- Zika virus disease
- Relapsing fever
- Unknown-agent

These diseases pose significant public health risks and require appropriate tests for surveillance and diagnosis. The distribution of these diseases varies geographically; however, several pose a risk for African countries due to the potential for spread through travel and other factors after an outbreak. While not all countries will be actively testing for all of these diseases, active and passive surveillance is recommended and the capacity to rapidly mobilize testing and outbreak response for each disease should be established. This is considered an essential core capacity of epidemic preparedness for member states. AU member states are able to prioritize diseases based on local epidemiology using this risk-ranking methodology and other tools (2-4).

Testing for Epidemic-Prone Diseases

The section below provides recommendations for laboratory capacity that AU member states should establish based on local epidemiology to ensure diagnostic readiness to respond to an outbreak of a priority epidemic-prone disease. Specific testing requirements, protocols and recommended technologies for each disease are provided to assist member states with identifying reliable tests for rapid identification in the event of an emerging outbreak. In addition, as certain groups of diseases with similar pathology or genetic composition present with similar symptoms (e.g. respiratory infections: COVID-19, influenza, RSV), or are part of common surveillance activities (e.g. surveillance for arboviruses), considerations for testing within these groups are provided.

This guidance provides recommendations on the use of integrated testing and multiplex testing. The definitions of these terms are as follows.

Integrated testing, for this guidance the term ‘integrated testing’ refers to the use of the same instrument to test for multiple different infections, provides the advantage of expanding the testing capability of existing laboratories with instruments deployed originally for single diseases, such as COVID-19, influenza, HIV or TB. Conducting additional disease tests on these instruments is recommended as an effective way to rapidly expand epidemic testing capabilities, except where biohazard requirements dictate dedicated instruments.

Multiplex testing, for this guidance the term ‘multiplex’ refers to the ability to test for multiple pathogens in a single sample. This enables faster and more efficient identification and surveillance amongst diseases that occur at the same time or have similar symptoms. Multiplex testing results also provide clinicians with local epidemiologic information with which to make evidenced based differential diagnosis. AU member states are advised to pursue multiplex testing when possible, in these situations, provided specific multiplex reagents are available and affordable.

A summary of the recommended diagnostic test types for priority epidemic-prone diseases is outlined in Table 4. These include individual and multiplex nucleic acid tests, point-of-care nucleic acid tests, immunological assays, including ELISAs and rapid tests (both antibody and antigen), culture systems and genome sequencing. Details on recommended tests for each disease are provided below.

Table 4. Recommended diagnostic tests for epidemic-prone diseases

	Single target NAT	Multi-plex NAT	Point-of-care NAT	Rapid antigen test	IgM/IgG ELISA/RDT	Culture/microscopy	Sequencing
<i>Influenza-like illness</i>							
SARS-CoV2	✓	✓	✓	✓			✓
RSV	✓	✓	✓	✓			
Influenza	✓	✓	✓	✓			
Avian influenza	✓						
<i>Arboviruses</i>							
Dengue	✓	✓		✓	✓		✓
Zika	✓	✓			✓		
Chikungunya	✓	✓			✓		
Yellow Fever	✓	✓		✓	✓		

	Single target NAT	Multi-plex NAT	Point-of-care NAT	Rapid antigen test	IgM/IgG ELISA/RDT	Culture/ microscopy	Sequencing
Meningitis							
N. meningitidis	✓	✓					
S. pneumoniae	✓	✓					✓
H. influenzae	✓	✓					✓
Diarrhoeal Diseases							
Cholera				✓		✓	✓
Haemorrhagic fevers							
CCHF	✓	✓					✓
Ebola	✓	✓	✓	✓			✓
Lassa fever	✓	✓		✓	✓	✓	✓
Marburg	✓	✓					✓
Rift Valley Fever	✓				✓		✓
Mpox	✓		✓	✓			✓
Poliovirus	✓					✓	✓
Anthrax	✓	✓				✓	✓
Measles	✓				✓		✓
Plague		✓		✓			✓

Viral Haemorrhagic Fevers

Major causes of concern are Crimean-Congo Haemorrhagic Fever virus, Dengue virus, Ebola (Zaire and Sudan virus strains), Lassa Fever virus, Marburg virus, Rift Valley Fever virus.

In the event of suspected cases of viral haemorrhagic fever, or for surveillance, where possible use rapid antigen tests and multiplex diagnostic panels (nucleic acid or immunoassay) (5). If positive, test other symptomatic individuals amongst family members and close contacts for the identified pathogen. If negative, continue surveillance in the community. The possibility of viral haemorrhagic fever should be maintained until an alternative diagnosis is confirmed. Given the low prevalence of many of these diseases, a confirmatory test result is likely necessary for many circumstances. Once the panel has identified which disease or diseases are causing the outbreak, countries facing an outbreak can switch to disease-specific testing. The testing approach for each disease is outlined below.

Crimea-Congo Haemorrhagic Fever

Nucleic acid tests, e.g. Reverse transcription polymerase chain reaction (RT-PCR) and antigen capture assays are recommended for Crimean-Congo Haemorrhagic Fever (CCHF) and should be established at reference laboratories (6-9). In addition, IgM ELISA and IgG ELISA assays are available and can be used as adjunct tests. Rapid antigen and antibody tests are currently not available. Patient samples should be handled under maximum biohazard containment conditions and virus inactivation methods should be used for in vitro testing. Virus culture is also possible but may be impractical in most settings or not fast enough for outbreak management.

Dengue

Nucleic acid testing is the gold standard for dengue diagnosis and this capacity should be established at reference laboratories and at laboratories in high-risk dengue areas (9-11). Commercial RT PCR kits are available as well as multiplex assays. In addition, rapid antigen tests and ELISAs based on the NS1 protein with adequate performance are available and can be used at peripheral facilities to enable rapid diagnosis and response activities. Both PCR and antigen tests can be used during the first week after the start of symptoms. IgM antibody tests for dengue virus can be a useful alternate tool for diagnosis after the initial clinical stage and are used for surveillance. IgM ELISA capability can be established at reference laboratories if needed. Tests to detect IgM or IgG antibodies can be compromised by cross-reactions with other viruses and by past infections and so can only be used with an understanding of the epidemiologic context. Virus isolation by culture is also a sensitive diagnostic method, however, is not a fast method for outbreak situations and requires adequate laboratory infrastructure as such it might be reserved for reference or research testing.

Ebola virus

Nucleic acid testing (on blood or oral fluid samples) is the gold standard for Ebola testing and one of the most commonly used methods for diagnosing this disease in the event of an outbreak because of its high sensitivity and specificity (12,13). Ebola RT-PCR capacity should be established at reference laboratories, as well as within laboratories in high-risk Ebola regions. A number of reliable PCR tests are available. In addition to laboratory PCR platforms, point-of-care PCR technologies are available and enable rapid, decentralized testing. Rapid antigen tests for Ebola are also available and are recommended for screening purposes at more peripheral sites as part of surveillance and early detection activities. Antigen-positive cases should be isolated, and their status confirmed with PCR. Whole blood or oral fluid samples should be treated as extremely biohazardous.

Marburg virus

Nucleic acid testing RT-PCR (based on NP, L, and GP genes) is a practical and reliable gold standard for Marburg virus testing and should be established at reference laboratories to confirm suspected cases (14,15). Antigen detection ELISAs and IgM antibody ELISAs are also useful options for diagnosis in the early stages of infection and can be established at reference laboratories. IgG-based ELISAs can also be used after recovery. Reference laboratories should also establish access to sequencing capacity to type new virus outbreaks. Virus isolation by cell culture requires BSL4 facilities that may not be feasible in most settings and is not always practical for outbreak control.

Lassa Fever

Capacity for nucleic acid Lassa Fever testing with RT-PCR should be established at reference laboratories to enable diagnosis of suspected cases within the first 1-2 weeks of clinical symptoms (16,17). Lassa virus diversity can impact the performance of PCR-based assays, and hence nucleoprotein antigen tests and IgM tests are also useful tools to establish at reference laboratories to help overcome strain diversity challenges and diagnosis after the clinical stage. In addition, rapid antigen tests can be deployed at peripheral facilities to enable rapid response in the event of an outbreak. RT-PCR, antigen and IgM tests are available, but careful selection is needed. Multiplex tests for Lassa Fever, Ebola, and other viruses to enable differential diagnosis amongst infections with common symptoms are also becoming available.

Virus isolation by cell culture is the gold standard and most sensitive test but requires BSL4 facilities which are not available in most settings and are not a fast or practical diagnostic tool for use during outbreaks. Antibody-based tests can be useful for recovered cases but may also detect previous infections due to the persistence of antibodies, so an understanding of the epidemiologic context is needed for their use. Lassa fever specimens are hazardous and should be handled with extreme care.

Rift Valley Fever Virus

Capacity for Rift Valley Fever diagnosis using nucleic acid tests should be established at reference laboratories in coordination across human and animal health departments (18,19). RT-PCR enables diagnosis within the first week of clinical symptoms and at least two stringent regulatory-approved commercial test kits are available. Serological IgM ELISA and IgG ELISA tests are also available, and capability should also be established at reference laboratories to enable diagnosis after the clinical stage. Reference laboratories should also establish access to sequencing to enable genetic characterization of RVF virus samples occurring in new outbreaks. Virus isolation is possible but is an impractical diagnostic method for outbreak management, except in selected settings. Laboratory specimens may be hazardous and must be handled with extreme care.

Respiratory Infections

Major causes of concern: SARS-CoV2, influenza type A and type B, RSV.

Diagnostic capacity for SARS-CoV2 should be widely accessible across health facilities and for at-home testing with rapid antigen tests (20,21). In addition, capacity for nucleic acid tests for SARS-CoV2 should be present at selected laboratories, and access to sequencing for surveillance for variant monitoring should be in place. Quality-assured diagnostic tests for SARS-CoV2 are commercially available.

For influenza type A and B, RT-PCR and typing capacity should be accessible through reference laboratories for surveillance of new outbreaks and the emergence of new strains (22). Reliable influenza

PCR and typing tests are commercially available. Rapid antigen tests for influenza are also commercially available but have lower sensitivity than RT-PCR and are not used widely for surveillance. However, they may be useful in the event of a widespread outbreak.

RSV testing is conducted mainly for surveillance purposes and capability for RT-PCR testing needs to be increased, as well as access to reliable rapid antigen testing (23). These tests are commercially available.

Due to common symptoms amongst these viruses and other respiratory infections, both clinical management and surveillance would benefit from the use of multiplex panel testing to rapidly determine which infection is occurring. Multiplex tests for combinations of these respiratory viruses are becoming increasingly available, in both laboratory RT-PCR and on small point-of-care instruments.

Watery Diarrhoea

Major cause of concern: Cholera

The isolation and microbiological culture of *Vibrio cholerae* from stool followed by serotyping to detect the 01 and 0139 pathogenic strains is the gold standard for the diagnosis of cholera and should be established at reference and other microbiology laboratories (24,25). In addition, because culture is a slow method, rapid antigen tests for stool are recommended and should be available for deployment on site in the event of a suspected cholera outbreak. Although rapid tests have lower sensitivity and specificity than culture, they enable the rapid detection of an emerging outbreak and the institution of public health measures while confirmation by culture is underway. In addition, nucleic acid testing and typing capacity can be established at reference and other laboratories responsible for confirmation of cholera, to enable faster confirmation.

As other conditions can cause watery diarrhoea, multiplex panel tests are available that can aid differential diagnosis for Rotavirus, Norovirus, Cholera, Polio and other infections if clusters of severe cases occur (26,27).

Meningitis

Major cause of concern: *Neisseria meningitidis* (meningococcal disease)

Meningococcal meningitis is a leading cause of community-acquired bacterial Meningitis. Diagnosis for *N. meningitidis* in patients with fever and neurological signs can be made with rapid antigen tests on cerebrospinal fluid (CSF) obtained by lumbar puncture (28,29). These tests detect the main serogroups and enable rapid on-site diagnosis. In addition, capacity for *N. meningitidis* microscopy or culture of CSF with serotyping should be available within routine clinical microbiology laboratories. Other infections can also cause meningitis, hence panel testing of CSF can help differentiate viral vs bacterial infections, such as *S. pneumoniae* and *H. influenzae*. If meningococcal disease is confirmed, further typing can determine if the infection is due to A,C,W,Y or X serogroups.

Arboviruses

Major causes of concern: Yellow Fever, Chikungunya, Zika, Dengue viruses.

Nucleic acid testing using RT-PCR is the most sensitive and specific diagnostic method for these flavivirus infections and should be prioritized to confirm infection within the first 7–10 days from the onset of symptoms (9-11, 30). Commercial single-plex tests are available. However, not all patients present for diagnostic testing during the viraemic phase. Detection of specific IgM and IgG by various methodologies is sensitive but less specific than viral detection methods due to cross-reactive epitopes within some families of arboviruses, thus confirmatory testing with specific assays is usually necessary. Population-based surveillance can use a multiplex IgM panel for Dengue, Zika, Chikungunya and Yellow Fever, followed by individual assays if needed.

Yellow Fever

Nucleic acid testing capacity for Yellow fever virus should be established at reference laboratories to confirm infection within the first 10 days from the onset of symptoms (31,32). Serological tools, such as IgM rapid tests and ELISAs can also be useful, although they suffer from cross-reactivity with other flaviviruses and vaccine induced antibodies, and if used should be followed up with confirmatory assays such as PCR. Rapid antigen tests for yellow fever have been developed and promise to be a useful tool.

While viral isolation in culture and immunohistochemistry are gold standards for yellow fever detection, these methods are not always practical as first-line diagnostic tools, especially in the context of an emerging outbreak or for surveillance.

Chikungunya

Capacity for nucleic acid testing should be established at reference laboratories for the diagnosis of Chikungunya virus infection within the first week of illness. A number of RT-PCR assays, antibody-based (IgM and IgG) ELISAs and rapid serological tests are commercially available, however careful selection based on independent performance studies and regulatory approval is required (33,34). Rapid antigen tests for the detection of virus during the acute clinical phase of infection have been developed but are not widely available, validated, or shown to detect all lineages. Culture can also be used but may be impractical in many settings.

Zika

Capacity for nucleic acid testing should be established within reference laboratories for the diagnosis of Zika within the first week of symptoms (10). Rapid antigen tests are currently not available. Serological IgM and IgG antibody rapid and ELISA tests are available and are useful especially after the clinical phase of infection when viral levels subside. However, these can suffer from cross-reaction with other flaviviruses, so local epidemiology needs to be considered. Culture can be used as a gold standard but may not be a practical diagnostic tool in most settings.

Mpox

Nucleic acid test capacity should be established at reference laboratories as the preferred diagnostic method for Monkeypox given its accuracy and sensitivity (35,36). Decentralization of testing is also preferred and rapid PCR tests for Monkeypox are available. Rapid antigen and antibody tests are available but current tests do not distinguish between other orthopox viruses, and so may not be useful. Optimal diagnostic samples for Monkeypox are from lesions - from the lesion roof, or fluid from vesicles and pustules, and dry crusts. PCR blood tests are usually inconclusive because of the short duration of viraemia relative to the timing of specimen collection after symptoms begin and should not be routinely performed in suspected patients. Mucosal swabs can also be tested, though a negative result does not preclude infection.

Poliovirus

National reference laboratories should maintain capacity for detection and typing of poliovirus and the ability to ship samples to regional reference laboratories. Nucleic acid-based polio tests should be used for the detection of poliovirus in specimens from the throat, faeces (stool), and occasionally cerebrospinal fluid (CSF) (37-39). RT-PCR also allows intratypic differentiation of possible wild strains from vaccine strains. The isolation of the virus in cell culture from stool samples is the most sensitive method. Genomic sequencing to confirm genotype and geographic origin requires advanced laboratory infrastructure which in many countries has been put in place to sequence SARS-CoV-2. Serology can be used in known unvaccinated patients.

Anthrax

Capacity to diagnose *Bacillus anthracis* infection in the blood, respiratory secretions, and skin lesions with nucleic acid tests should be established at reference laboratory level (40,41). Culture on swab samples can also be conducted where advanced infrastructure exists.

Measles

Measles is most commonly diagnosed using serologic tests for IgM antibodies or the detection of viral RNA by RT-PCR (42). Isolation of the virus in culture can also be used but is impractical in most settings. The approach to diagnosis differs depending on the regional prevalence of measles. Molecular analysis can also be conducted to determine the genotype of the measles virus.

Plague

Early diagnosis and treatment enable high cure rates for plague. Rapid antigen tests are recommended and are available for use on blood, sputum or pus from a swollen lymph gland (43). Real-time PCR and immunofluorescent staining are also available diagnostic methods.

Wastewater Surveillance

Surveillance of wastewater is an emerging strategy to provide an early warning system of the presence of pathogens or contaminants within a community. Samples can be collected from sewer-shed and tested using qualitative PCR and /or digital PCR to determine the presence and absence of pathogens. Metagenomic next-generation sequencing can also be performed on wastewater samples to determine if variants of concern are present. A positive sample can indicate the presence of infected individuals prior to symptoms or presentation for medical care. Wastewater surveillance provides population-level screening and can be used to inform quarantine decisions and other preventive measures. Wastewater surveillance is relevant for polio, Monkeypox, SARS CoV-2 and any enteric pathogen. Laboratory capacity for wastewater surveillance should be established at reference laboratories. Other environmental surveillance methods may be developed for priority pathogens and multiplex testing may be a useful screening tool.

Testing for Disease Surveillance

Based on the recommended tests for each pathogen described above, a summary of syndrome-based active and passive surveillance approaches for epidemic-potential pathogens is provided in Table 5. Surveillance approaches are based on the following definitions:

Active surveillance: Based on active efforts to gather data on the occurrence of disease, e.g. a survey for a disease agent
Passive surveillance: Data on disease occurrence is gathered passively from existing activities conducted for other purposes, e.g. results from routine clinical testing

This guidance provides details on the sampling strategy, frequency of sampling and specimen types, the recommended location of testing capacity within a tiered health system, and the types of tests and actions recommended for each disease syndrome.

Table 5. Summary of testing approaches for active and passive surveillance

Active surveillance						
Syndrome	Major causes	Sampling strategy	What test to use and specimen	Time to result	Frequency of sampling	Action on result
Influenza-like illness. Year-round surveillance	SARS CoV-2, RSV, Flu, Avian Flu	Sentinel site in district hospital	NP/Nasal swabs. POC NAT	45 mins to 1hr	Monthly	Confirm RDT+ with NAT. Wastewater: disease spread and variant analysis
		Environmental surveillance	Wastewater samples, PCR (SARS-CoV2)	1-2 days		
		Community sites	Antigen RDT	15-20 mins		
Arboviral disease. Surveillance during the rainy season.	Dengue, Zika, Chikungunya, Yellow fever	District hospital	Blood. IgM ELISAs confirmed by NAT	45 mins to 1hr	Seasonal	Confirm IgM+ RDT+ with NAT. Vector control. Dengue, yellow fever vaccine
		Community sites	Blood. Multiplex IgM RDT	15-20 mins		
Meningitis. Surveillance during dry season.	N. meningitidis, S pneumoniae, H influenzae.	District hospital	CSF. Antigen RDT, vulture, sensitivity and typing	2-3 days	Seasonal	Antibiotics. Vaccine deployment.
		Community sites	CSF. Antigen RDT, POC NAT in a few selected sites	45 mins to 1hr		
Passive surveillance						
Diarrhoea (watery)	Cholera	District hospital	Stool. Antigen RDT, NAT for confirmation.	45 mins to 1 hr	Activated by single case	Hygiene and sanitation, clinical management of patients, vaccine deployment.
		Community sites	Stool. Antigen RDT	15-20 mins		
Haemorrhagic fever	CCHF, Dengue, Ebola, Lassa, Rift Valley fever, Marburg	Community sites	Antigen RDT	15-30 mins	Activated by single case	Blood samples for suspected haemorrhagic fever should be sent for NAT testing. A positive test will
		District hospital	POC NAT for confirmation,	45 mins to 1hr		

			(multiplex NAT if feasible)			activate public health control measures including vaccination where appropriate
Others						
	Poliovirus, Monkeypox, measles, plague	Regional/central level hospital	POC NAT for confirmation using samples from community sites. Active wastewater surveillance for polio	45 mins to 1hr	Activated by single case	Samples from community sites are sent to the regional/central level for confirmation. Positive case will activate public health control measures such as vaccination for polio, measles and Monkeypox. Antibiotherapy for plague.
		Community sites	RDTs available for plague and Monkeypox. Send other samples to closest testing lab			

Recommended Laboratory Capacity

Based on the recommended test outlined above, requirements for tiered networks of public health laboratories to ensure preparedness, early detection, and rapid response for epidemic-prone diseases in African countries is described below. Five main categories of diagnostic tests are required for these networks, including the following:

- Nucleic acid amplification tests, lab-based or near-patient formats
- Antigen tests, ELISA or rapid point-of-care formats
- Antibody tests, laboratory ELISA and rapid point-of-care formats
- Culture
- Genomic sequencing

The general characteristics of these test types are summarized below.

Table 5. General characteristics of common test types used for epidemic-prone pathogens

	Detects	Accuracy	Cost	Ease of use	Time to result	Comments
Nucleic acid test	Pathogen DNA or RNA	√√√	\$\$\$	Laboratory	1-2 hours	Require instruments and trained operator
				Point-of-care (POC)	5 - 45 min	
Antigen Test	Pathogen protein	√√	\$\$	ELISA: high throughput lab	3 hours	POC tests available with or without instruments; minimal training
				POC: disposable single-use strips	15-30 min	
Antibody Test	Host antibody	√√	\$	ELISA: high throughput lab	3 hours	May give false positive results due to cross-reactivity
				POC: disposable single-use strips	15-30 min	
Genome sequencing	Pathogen nucleic acid	√√√	\$\$\$\$	Advanced laboratory	Days	Sequencing capacity is expanding
Bacterial culture	Pathogen Isolation	√√√	\$\$\$	Microbiology laboratory	Days	Routine clinical testing
Viral culture	Pathogen Isolation	√√√	\$\$\$\$	Facility for tissue culture	Days	Culture facility not widely available

AU member states are advised to work towards establishing adequate capacity for these testing platforms as a foundation for capability to diagnose epidemic-prone diseases. Capacity for specific disease tests within these testing platforms and how these are distributed across the levels of the national

health system should be dependent on local epidemiology, levels of risk, and national prioritization. Capacity for national priority tests should be established across a network of central reference laboratories and routine clinical laboratories for nucleic acid and serological immunoassays, and at district, primary health care and community levels for rapid immunoassays and point-of-care nucleic acid tests. Surveillance testing should also be conducted at sentinel sites using different test types. In addition, capacity for certain specialized tests (e.g. genome sequencing and viral culture) can be established through partnerships with regional reference laboratories such as Africa CDC centres of excellence and WHO reference laboratories.

Specific recommendations for each type of test are provided below.

Nucleic Acid Amplification Tests

Nucleic acid amplification testing (NAT or molecular testing, e.g. real time PCR) is a frontline diagnostic method for both surveillance and confirmatory diagnosis for the majority of epidemic-prone diseases in African countries, including: Crimean-Congo Haemorrhagic Fever, Chikungunya, Lassa Fever, Ebola, Rift Valley Fever, Marburg disease, Dengue, Yellow Fever, Zika, influenza, avian influenza, and RSV. RT-PCR also provides alternate or important adjunct tests for *Neisseria meningitidis*, cholera and SARS-CoV2. Molecular tests are highly sensitive and specific within the first 1–2 weeks after the start of clinical symptoms.

In addition, nucleic acid test systems are required for environmental (e.g. wastewater) surveillance (for sequencing and for digital PCR) and as an essential part of pathogen genomic sequencing assays for priority epidemic-prone infectious agents. As such, molecular diagnostics should be part of the core capacity of national reference laboratories and selected laboratories within member states. These laboratories should establish and maintain capacity to run nucleic acid tests for each of the epidemic prone diseases relevant for the country, subscribe to external quality assurance schemes, and maintain this capacity in a state of readiness even when outbreaks are not occurring. Testing for different epidemic prone infections can often be integrated on the same PCR instruments, except for certain highly infectious and pathogenic agents which require dedicated instruments.

Nucleic acid tests for most pathogens are available for laboratory-based open PCR instruments, with some assays available on fully automated laboratory instruments and on automated rapid point-of-care instruments (e.g. Ebola, Monkeypox, influenza). Open PCR instruments allow test reagents to be procured from different suppliers, providing a wider range of supplier options which may be important in the event of an outbreak. However, open PCR requires more manual steps than automated testing and hence laboratories should institute strict protocols and quality assurance systems.

Importantly, multiplex PCR assays are now available for certain panels of agents and are becoming more accessible. Multiplex PCR assays are useful to improve the efficiency of surveillance and to enable the rapid differential diagnosis of patients that present with symptoms that are common to multiple infections. It is important to ensure that multiplex testing panels and algorithms are carefully designed to ensure that test results are useful. Evaluations of the use of multiplex tests are recommended.

Rapid antigen tests

Rapid antigen tests are important tools for surveillance and early detection, especially at peripheral sites where new outbreaks often first occur. Where possible, rapid diagnostic tests are preferable as they can better enable quicker response with outbreaks of known agents and facilitate timely patient management, including non-pharmaceutical interventions such as isolation and quarantine. They allow implementation at community level and can strengthen community engagement. Because of their ease of use, they do not require significant laboratory infrastructure to deploy and can be used at a wide range of decentralized locations. Like RT-PCR tests, antigen tests are sensitive during the first 1–2 weeks after the start of clinical symptoms. For certain pathogens, rapid antigen tests provide an initial screen that if positive, needs to be followed by a confirmatory test such as nucleic acid testing, however they enable early action to be taken to provide care and prevent spread. Antigen tests are less sensitive than nucleic acid tests, hence negative antigen test results do not always rule out infection and additional samples for testing may be needed if clinical and epidemiologic suspicion is high. A number of rapid antigen tests are available for different epidemic prone infections, including SARS-CoV2, dengue, Ebola, Lassa fever, cholera, plague, influenza and RSV. Depending on the disease, certain tests are diagnostic (e.g. SARS-

CoV2) while others are used for screening or surveillance purposes and require confirmation with a molecular assay (e.g. Ebola) or culture (e.g. cholera) . The use of rapid tests should follow careful biohazard precautions when applied to potential high-risk samples, and special training of health care workers at health facilities is needed to ensure biosafety procedures are followed.

Testing systems for rapid antigen tests for epidemic prone infections should be integrated as far as possible with current capacities used for malaria, HIV, and SARS-CoV2 rapid testing, as opposed to separate systems and staff for different diseases. Healthcare workers should be trained on the use of different rapid tests, including biosafety requirements and sample transport for confirmation of positive cases. However, within these integrated testing systems, result reporting procedures will differ by disease, with dedicated priority reporting of epidemic disease test results.

Antibody-based tests

Antibody-based serology tests for IgM or IgG are useful additional assays for epidemic-prone disease surveillance and clinical testing. They are generally cheaper than RT-PCR and rapid antigen tests and allow larger volumes of tests to be run at reference and other laboratories in high incidence regions. In some settings, rapid antibody detection tests are also important diagnostic tools, for example for the surveillance of arboviruses. IgM-based rapid tests can help detect acute infection in the first few weeks after exposure. The decision on when to use a serology test should be done disease by disease, as these tests are not available or recommended for all epidemic prone diseases in Africa. For example, certain IgM and IgG antibody tests suffer from cross-reactivity and IgG assays may detect a past rather than current infection, or vaccination. Some antibody-based tests are commercially available, while other assays are laboratory-developed tests or for research use. Serology testing equipment, e.g. for ELISA, are widely available and used for other diseases, and so integration of testing across different diseases is recommended, except where biosafety requires dedicated instruments. Like PCR and rapid immunoassays, the use of ELISA tests should follow careful biohazard precautions.

For certain pathogens, more sophisticated immunological assays can also be useful to assist in confirmatory testing, for surveillance or clinical diagnosis at national reference laboratories, such as immunohistochemistry. It is recommended that the use of these assays is decided on a case-by-case basis if considered the preferred method and feasible, and if other diagnostic options are not available.

Culture

Microbiology laboratories are an essential component of epidemic disease testing capacity for both routine clinical diagnosis, confirmatory and drug resistance testing, and for surveillance, particularly for bacterial pathogens. Culture systems for biosafety level 3 and 4 biohazardous agents such as viral haemorrhagic fevers also provide important confirmatory capacity for reference laboratories but are not essential for disease management and rapid epidemic control. With a few exceptions, PCR-based tests are able to provide routine confirmatory testing for most disease agents. However, access to BSL3/4 culture capacity is important to establish for national health institutes and reference laboratories and can be set up either in country if resources permit, or through linkages with regional centres of excellence and reference laboratories, together with systems for safe packaging and transport of specimens.

Genome sequencing

Genetic sequencing is growing in importance as a tool to type pathogens and to track and analyse genetic variations that contribute to changes in disease trends and the risk of outbreaks and spread (45,46). Certain pathogens exhibit high genetic diversity or are subject to key genetic changes either of which can influence the severity of disease or the course of an epidemic. As a result of the COVID-19 pandemic and other diseases, increased sequencing capacity is being established across the continent. Access to sequencing tools is important for several epidemic-prone pathogens and is part of routine surveillance and epidemiologic investigation per testing policies, including SARS-CoV2, Ebola virus, Marburg virus, and for antimicrobial resistance.

It is recommended that national reference laboratories responsible for outbreak analysis establish access to genomic sequencing capacity either on-site or via a regional sequencing centre. The infrastructure and costs required for sequencing are significant and appropriate resources should be made available. The use of sequencing systems should follow strict biosafety procedures. Sequencing results for certain

pathogens and variants of concern should be submitted to regional or international tracking systems. Member states are advised to establish capacity and training for bioinformatic analysis of sequence data to enable rapid decision making in the event of an outbreak.

Where adequate national genetic sequencing capacity is not available, this can be accessed via Africa CDC centres of excellence and WHO reference laboratories, where high volume pathogen sequencing systems are available. This includes pathogen-agnostic systems for pathogen identification in cases of diseases with unknown agent.

Laboratory systems strengthening for epidemic preparedness

Guidance is provided here to Member States on establishing and strengthening laboratory infrastructure and health systems for epidemic testing.

Regulatory capacity

In the event of an outbreak, rapid regulatory review of new diagnostic products is often needed. National regulatory systems should establish policies and procedures for rapid review, as they look to other existing stringent regulatory approvals to inform local review.

Diagnostic network optimization and community-based surveillance

The COVID-19 pandemic resulted in widespread use of laboratory-based nucleic acid amplification technologies such as real-time PCR. While this use has reduced significantly, large numbers of laboratory staff have been trained on the use of these systems, building on capacity established earlier for HIV and tuberculosis. A wide range of manufacturers of test reagents have developed manufacturing and supply capacity that could help meet testing needs in African countries, including local manufacturers. Together, this capacity can be leveraged to support testing for epidemic-prone pathogens.

Member states are advised to ensure that available nucleic acid amplification laboratory instruments and reagents can be rapidly mobilized for testing in the event of an outbreak, and that there is with sufficient laboratory capacity for continuous testing in the event of instrument breakdown or a surge in test demand. This includes designing and implementing a network of instruments across different laboratories to provide reliable and rapid access to testing should an outbreak occur. Multiplex instruments and near-patient molecular platforms can also play an important role, and in some situations ELISA tests and culture are useful.

For certain pathogens or tests, the national testing network should extend to regional reference laboratories with the capacity to conduct highly specialized assays, typing, or confirmatory tests. For example, advanced sequencing systems and culture capacity are available through Africa CDC Centres of Excellence and WHO regional reference laboratories. Testing policies, agreements and procedures should be pre-established to facilitate rapid referral of samples to regional reference laboratories for testing when needed and the return of test results, following available guidance.

At the community level, member states are advised to strengthen capacity for rapid testing and to train and capacitate healthcare workers at primary health care and community health centers to screen for certain epidemic-prone diseases with clinical algorithms and rapid tests (e.g. rapid antigen tests or rapid nucleic acid tests) at community-level (see Table 5). Strengthened capacity at this level will help improve surveillance and the early detection of new outbreaks and epidemic trends. This testing should be integrated into national surveillance systems as well as routine primary health care clinical testing systems for other diseases. Testing at this level should be coupled with community awareness programs for priority diseases, especially in areas of higher risk. Test results should be communicated promptly to national public health institutes, reference laboratories, or epidemic control centers, as per local national protocols. Testing capacity at community level should be integrated with central

laboratory capacity to establish a network for testing for national priority epidemic-prone diseases across the country and levels of the health system.

Member States are advised to design and implement biosafety and biosecurity sample referral systems that connect peripheral health facilities across the country to the national reference laboratory and other laboratories responsible for epidemic disease testing for different agents, including regional and international laboratories. This should follow guidance for the transport of infectious substances. Ideally, this system should be integrated and used as one common system rather than separate sample transport systems for different diseases. However, certain agents may require dedicated transport systems, however, e.g. extreme biohazardous agent transport and samples requiring immediate transfer or rapid confirmation.

Quality

Testing programs for epidemic-prone diseases should be subject to rigorous quality management and assessment to ensure accuracy and reliability. This includes the need to ensure quality testing of laboratories and test operators identified in the network to test for epidemic prone diseases, participation in external quality assurance and proficiency testing programs, training on good laboratory practices and laboratory management, and laboratory accreditation.

Training

Establishing and maintaining adequate numbers of trained health care workers and laboratory technicians to recognize symptoms, collect and ship samples, run tests and to analyze and report results for all relevant epidemic-prone diseases is required. Training in quality management systems, laboratory management, data management and bioinformatics, biosafety and biosecurity, and in outbreak management should also be planned for. Once trained, healthcare workers and laboratory staff will be able to mobilize testing rapidly in the event of an outbreak. Due to the unpredictable nature of outbreaks, systems for periodic retraining of clinical and laboratory staff should be established. Training in both rapid tests and specialized laboratory-based nucleic acid, culture, serology, and sequencing assays is needed, as well in data analytics and bioinformatics, biosafety procedures and biohazardous sample referral, and epidemic disease outbreak management and coordination frameworks. Training programmes should be made available locally and can be accessed regionally, for example through Africa CDC Centres of Excellence and WHO regional reference laboratories.

Supply chain

Rapid access to high quality test reagents is critical at the time of an outbreak. Member States are advised to establish and maintain supply chain systems for relevant disease tests, including identifying suppliers of high-quality tests, establishing minimum criteria for technology selection, negotiating affordable pricing and pre-securing assured supplies in the event of an outbreak. Also necessary are systems for regulatory pre-approval of tests before outbreaks occur, and advance plans for local distribution and storage, and the stockpiling certain high demand tests if necessary. As seen with SARS-CoV2 testing, access to test kits can be severely challenging early in an outbreak when testing needs to be started or rapidly scaled up. Local manufacturing and established agreements with local suppliers may help improve access to tests and help ensure rapid availability when outbreaks occur. For certain diseases, commercially available tests are not easily available, or no multiplex assays exist. New diagnostic test development is needed for these diseases and should be prioritized within research and development efforts.

There are tests with stringent regulatory approval available for most priority epidemic-prone pathogens. Member states are advised to maintain a list of approved tests. However, in some cases, the available suppliers of test kits for certain diseases may not be known, or the quality of available test kits may be unclear (e.g. with locally-manufactured tests), and this can limit testing

implementation. For these situations, strengthened regulatory systems are needed, supported by policies for rapid, streamlined regulation in the event of an outbreak. Member states can refer to other lists of stringent regulatory-approved or pre-qualified tests if needed.

Data systems

Effective surveillance and disease outbreak response is dependent both on laboratory capacity and functional data systems that rapidly communicate test results in order to trigger outbreak response activities. Member States are advised to establish connected diagnostics systems that capture and transmit test results once validated, from both laboratories and community settings, and especially for rapid tests which are often not adequately connected to laboratory information and digital data systems.

Biosafety and biosecurity

Certain pathogens pose a significant biosafety and biosecurity risk. To limit risk to patients, health care workers, and the general population biological specimens for testing should be handled according to established laboratory and sample transport and handling biosafety protocols. High-risk samples should be packaged using the triple packaging system when transported nationally and internationally. Laboratory testing on non-inactivated samples should be conducted under maximum biological containment conditions. Testing results should also be handled appropriately and reported as per national guidance to ensure effective epidemic control.

Annex

Survey of Current Laboratory Capacity

To assess current laboratory capacity for the list of priority epidemic-prone diseases, a self-reported survey was conducted across national laboratories in Africa. Responses were received from 17 member states with geographical representation from all regions of Africa (Table 2). The findings from the survey are described below.

Table 1. Countries participating in the survey of laboratory capacity

Region	Member State
Eastern	Federal Republic of Somalia
	Republic of Madagascar
	FDR of Ethiopia
Central	Republic of the Central African Republic
Southern	Republic of South Africa
	Kingdom of Eswatini
	Kingdom of Lesotho
	Republic of Mozambique
	Republic of Malawi
Western	Republic of Sierra Leone
	Republic of Liberia
	Republic of Gambia
	Republic of Cabo Verde
Northern	Islamic Republic of Mauritania
	Sahrawi Republic

Testing Capacity

Respondents were asked to rank their capacity to diagnose the priority epidemic-prone diseases on a five-point scale from 1 – 5, with 5 being the highest. Based on the responses, seven diseases, COVID-19, poliovirus, measles, Monkeypox, cholera, meningitis and rabies emerged as having the highest level of testing capacity, reflecting past prioritization and investment in testing for these diseases in the responding countries. Diagnostic capacity was ranked as intermediate for a further eight diseases and low for the remaining five diseases (Rift Valley Fever, Crimean Congo haemorrhagic fever, plague, dengue fever, and Zika virus disease (Table 2).

Table 2. Reported national testing capacity for priority epidemic-prone diseases in Africa

Testing capacity		
<i>High</i>	<i>Intermediate</i>	<i>Low</i>
COVID-19	Ebola virus disease (Zaire)	Rift Valley fever
Poliovirus	Anthrax	Crimean-Congo Haemorrhagic fever
Meningitis	Chikungunya	Plague
Measles	Yellow fever	Dengue fever
Rabies	Ebola virus diease (Sudan)	Zika virus diease
Mpox	Avian influenza	
Cholera	Marburg virus	
	Respiratory syncytial virus	

Laboratory capacity correlated with the reported level of priority for each disease (Figure 1).

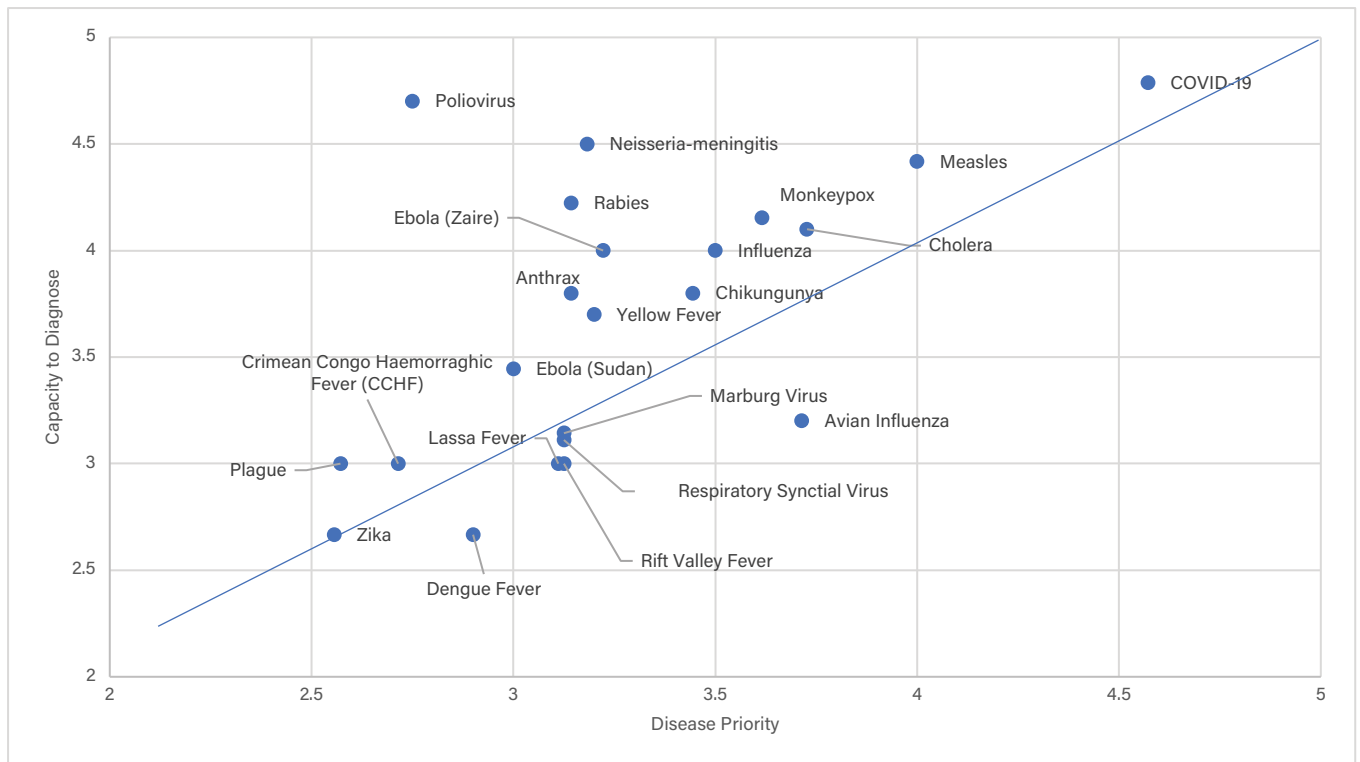


Figure 1. Reported testing capacity for diseases by priority (5 is the highest)

Disease Surveillance

Respondents were asked whether they have existing surveillance programs for these diseases (passive or active surveillance). The results correlate with the reported testing capacity and are shown below in Figure 2.

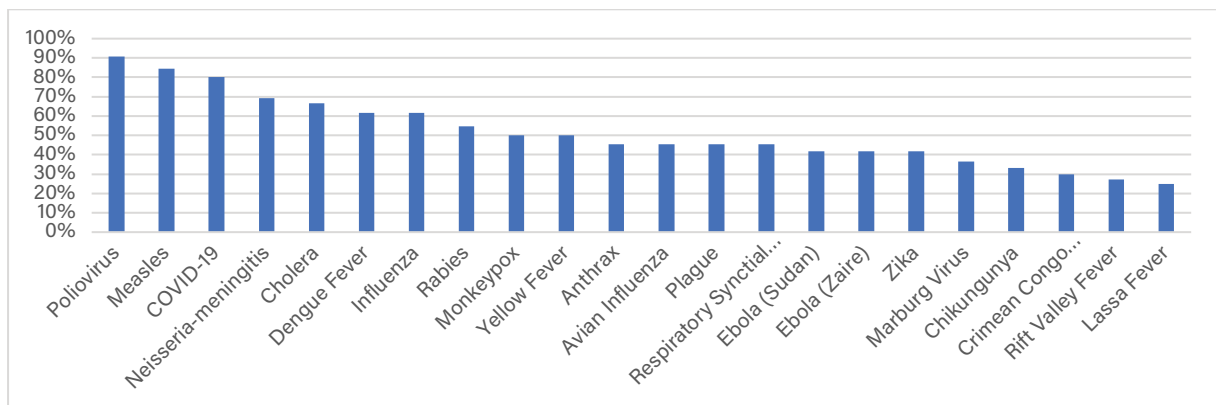


Figure 2. Proportion of responding countries with surveillance programs for priority diseases

Diseases with the highest reported surveillance were poliovirus (91%), measles (85%), COVID-19 (80%). Diseases with the lowest reported surveillance were Lassa fever (25%), Rift Valley Fever (27%) and Crimean-Congo haemorrhagic fever (30%).

Integrated and Multiplex Testing Capacity

Most countries responding to the survey conducted limited multiplex testing. The most common multiplex combinations were SARS-CoV2/Influenza and SARS-CoV2/influenza/RSV reported in six out of 15 countries. Nine countries reported doing no multiplex testing. However, the member states overall reported interest in establishing multiplex testing capacity for the following:

- Respiratory panel (SARS-CoV2, influenza, RSV)
- Arbovirus panel (Chikungunya, Dengue, Yellow Fever, Zika)
- Fever/viral haemorrhagic fever (Crimean-Congo haemorrhagic fever, Ebola, Lassa Fever, Marburg, Rift Valley Fever)
- Meningitis (*Neisseria meningitidis*, *Streptococcus pneumoniae*, *Haemophilus influenzae*)

This list reflects the responses of the survey participants and not necessarily the priorities of all countries.

Epidemic preparedness gaps

Respondents highlighted several diagnostic capacity gaps that impact their epidemic preparedness and ability to respond to new outbreaks. Human resources (staff and staff training), laboratory equipment and test supplies, and operational capacity of the health systems were highlighted as the most significant challenges. Specific needs and requests for support within these areas are detailed in Table 3.

Table 3. Gaps in laboratory capacity reported by survey participants

Epidemic preparedness laboratory capacity gaps		
Human resources and skills	Equipment and supplies	Systems strengthening
Staff shortages	Laboratory equipment	Bioinformatics
Outbreak response management	Nucleic acid test systems and kits	Outbreak management systems
Data and IT systems	Multiplex testing systems and kits	Equipment calibration and maintenance
Genome sequencing and metagenomics	Functional microbiology capacity and networks	Supply chain
Microbiology	Genomic sequencing equipment	Accreditation
Quality management	Test kits and supplies to prevent stock outs	Disease X (unknown agent) testing protocols
Molecular biology		International outbreak visibility and connections between laboratories and institutes
Training (e.g. bioinformatics and outbreak management)		

References

1. Phoobane P, Masinde M, Mabhaudhi T. Predicting Infectious Diseases: A Bibliometric Review on Africa. *Int J Environ Res Public Health*. 2022;19:1893. <https://pubmed.ncbi.nlm.nih.gov/35162917/>.
2. Africa CDC. Risk ranking and prioritization of epidemic-prone diseases; First Edition, 2022. Available at: <https://africacdc.org/download/risk-ranking-and-prioritization-of-epidemic-prone-diseases/>.
3. ECDC tool for the prioritization of infectious disease threat. <https://www.ecdc.europa.eu/en/publications-data/ecdc-tool-prioritisation-infectious-disease-threats>.
4. WHO. Strategic toolkit for assessing risks: a comprehensive toolkit for all-hazards health emergency risk assessment. Geneva: World Health Organization; 2021. <https://www.who.int/publications/i/item/9789240036086>.
5. Fogartaigh CN, Aarons E. Viral haemorrhagic fever. *Clin Med (Lond)*. 2015;15:61-6.
6. WHO. Crimean-Congo Haemorrhagic Fever. May 23, 2022. Available at: <https://www.who.int/news-room/fact-sheets/detail/crimean-congo-haemorrhagic-fever>.
7. Mazzola LT, Kelly-Cirino C. Diagnostic tests for Crimean-Congo haemorrhagic fever: a widespread tickborne disease. *BMJ Glob Health*. 2019;4:e001114.
8. CDC. Crimea-Congo Hemorrhagic Fever. Diagnosis. Available at: <https://www.cdc.gov/vhf/crimean-congo/diagnosis/index.html>.
9. WHO Dengue and severe dengue. March 17, 2023. Available at: <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>.
10. WHO. Laboratory testing for Zika virus and dengue virus: interim guidance. July 14, 2022. Available at: https://www.who.int/publications/i/item/WHO-ZIKV_DENV-LAB-2022.1.
11. PAHO. Guidelines for clinical diagnosis and treatment of Dengue, Chikungunya and Zika. November 9, 2021. Available at: <https://www.paho.org/en/documents/guidelines-clinical-diagnosis-and-treatment-dengue-chikungunya-and-zika>.
12. WHO. Ebola virus disease. February 23, 2021. Available at: <https://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease>.
13. Broadhurst MJ, Brooks TJG, Pollock NR. 2016. Diagnosis of Ebola virus disease: past, present, and future. *Clin Microbiol Rev* 29:773–793.
14. WHO. Marburg virus disease. August 7, 2021. Available at: <https://www.who.int/news-room/fact-sheets/detail/marburg-virus-disease>.
15. CDC. Marburg virus disease. Diagnosis. August 13, 2021. Available at: <https://www.cdc.gov/vhf/marburg/diagnosis/index.html>.
16. WHO. Lassa fever. July 21, 2017. Available at: <https://www.who.int/news-room/fact-sheets/detail/lassa-fever>.
17. Mazzola LT, Kelly-Cirino C. Diagnostics for Lassa fever virus: a genetically diverse pathogen found in low-resource settings. *BMJ Global Health* 2019;4:e001116.
18. WHO. Rift Valley fever. July 19, 2018. Available at: <https://www.who.int/news-room/fact-sheets/detail/rift-valley-fever>.
19. Petrova V, Kristiansen P, Norheim G, Yimer SA. Rift valley fever: diagnostic challenges and investment needs for vaccine development. *BMJ Glob Health*. 2020; 8:e002694.
20. Africa CDC. Revised Covid-19 testing strategy. Second edition. August, 2022. Available at: <https://africacdc.org/download/revised-covid-19-testing-strategy-second-edition-june-2022/>.
21. WHO. Antigen detection in the diagnosis of SARS-CoV2. Interim guidance. October 9, 2021. Available at: <https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2-infection-using-rapid-immunoassays>.
22. WHO. WHO information for molecular detection of influenza viruses. February, 2021. Available at: https://cdn.who.int/media/docs/default-source/influenza/molecular-detection-of-influenza-viruses/protocols_influenza_virus_detection_feb_2021.pdf?sfvrsn=df7d268a_5.
23. Teirlinck AC, Broberg EK, Stuwitz Berg A, et al. Recommendations for respiratory syncytial virus surveillance at the national level. *Eur. Respir J*. 2021;58:2003766.
24. GTFCC. Cholera outbreak response. Field manual. 2019. Available at: <https://www.gtfcc.org/wp-content/uploads/2020/05/gtfcc-cholera-outbreak-response-field-manual.pdf>.
25. GTFCC. Public health surveillance for cholera. Interim guidance. 2023. Available at: <https://www.gtfcc.org/wp-content/uploads/2023/02/gtfcc-public-health-surveillance-for-cholera-interim-guidance.pdf>.
26. Uwishema, O., Okereke, M., Onyeaka, H. et al. Threats and outbreaks of cholera in Africa amidst COVID-19 pandemic: a double burden on Africa's health systems. *Trop Med Health*, 2021;49, 93.
27. Gwenzi, W.; Sanganyado, E. Recurrent Cholera Outbreaks in Sub-Saharan Africa: Moving beyond Epidemiology to Understand the Environmental Reservoirs and Drivers. *Challenges*, 2019; 10: 1.
28. WHO. Meningitis. February 28, 2021. Available at: <https://www.who.int/news-room/fact-sheets/detail/meningitis>.
29. Cyrille H. Haddar , Aude Terrade , Paul Verhoeven. Validation of a New Rapid Detection Test for Detection of *Neisseria meningitidis* A/C/W/X/Y Antigens in Cerebrospinal Fluid. *Journal of Clinical Microbiology*, 2020, 5.
30. Adam A. and Jassoy C. Epidemiology and Laboratory Diagnostics of Dengue, Yellow Fever, Zika, and Chikungunya Virus Infections in Africa. *Pathogens* 2021, 10, 1324.
31. Africa CDC. Yellow fever. Available at: <https://africacdc.org/disease/yellow-fever/>.
32. Yellow fever laboratory diagnostic testing in Africa. Interim guidance. 2016. Available at: <https://apps.who.int/iris/bitstream/handle/10665/246226/WHO-OHE-YF-LAB-16.1-eng.pdf;jsessionid=33CE2872FA16B05C8F517F6FB03918EA?sequence=1>.
33. Johnson BW, Russell BJ, Goodman CH. Laboratory Diagnosis of Chikungunya Virus Infections and Commercial Sources for Diagnostic Assays. *J Infect Dis*. 2016;214:S471-S474.

34. Moreira J, Brasil P, Dittrich S, Siqueira AM (2022) Mapping the global landscape of chikungunya rapid diagnostic tests: A scoping review. *PLoS Negl Trop Dis* 16(7): e0010067.
35. WHO. Laboratory testing for Monkeypox virus. Interim guidance. May 23, 2022. Available at: <https://www.who.int/publications/i/item/WHO-MPX-laboratory-2022.1>.
36. Lim CK, Roberts J, Moso M, Liew KC, Taouk ML, Williams E, Tran T, Steinig E, Caly L, Williamson DA. Mpox diagnostics: Review of current and emerging technologies. *J Med Virol*. 2023;95:e28429.
37. WHO. Poliomyelitis. July 4, 2022. Available at: <https://www.who.int/news-room/fact-sheets/detail/poliomyelitis>.
38. WHO. Polio laboratory manual. 2004. Available at: <https://www.who.int/publications/i/item/WHO-MPX-laboratory-2022.1>.
39. CDC. Polio laboratory testing. March 14, 2023. Available at: <https://www.cdc.gov/polio/what-is-polio/lab-testing/index.html>.
40. CDC. Anthrax infection. Diagnosis and testing. July 23, 2021. Available at: <https://www.cdc.gov/anthrax/lab-testing/index.html>.
41. CDC/ASM/APHL. Basic diagnostic testing for level A laboratories. For the presumptive identification of *Bacillus anthracis*. 2002. Available at: <https://www.epa.gov/sites/default/files/2015-07/documents/cdc-anthrax.pdf>.
42. WHO. Measles outbreak toolkit. September 2022. Available at: <https://www.who.int/emergencies/outbreak-toolkit/disease-outbreak-toolboxes/measles-outbreak-toolbox>.
43. WHO. WHO guidelines for plague management: revised recommendations for the use of rapid diagnostic tests, fluoroquinolones for case management and personal protective equipment for prevention of post-mortem transmission. 2021. Available at: <https://apps.who.int/iris/handle/10665/341496>.
44. WHO. Environmental surveillance for SARS-COV-2 to complement public health surveillance. Interim Guidance. April 14, 2022. Available at: <https://www.who.int/publications/i/item/WHO-HEP-ECH-WSH-2022.1>.
45. WHO. Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health. 2021. Available at: <https://www.who.int/publications/i/item/9789240018440>.
46. WHO. WHO Guiding principles for pathogen genome data sharing. Geneva: World Health Organization. 2022. Available at: <https://www.who.int/publications/i/item/9789240061743>.



Africa Centres for Disease Control and Prevention
(Africa CDC)
Roosevelt Street, Old Airport Area, W21 K19
P. O. Box 3243, Addis Ababa, Ethiopia
Tel: +251 11 551 7700
Email: africacdc@africa-union.org