Technical guidance on laboratory operations for coronavirus disease (COVID-19) testing in the WHO African region

Version 1.0

I.   Introduction

On 31 December 2019, the World Health Organisation (WHO) was alerted to a cluster of atypical pneumonia cases in Wuhan, China [1]. Investigations revealed the circulation of a new coronavirus which was responsible for what is now known as Coronavirus disease 2019 (COVID-19). COVID-19 is a new disease, caused by a newly identified virus which was named Severe Acute Respiratory Syndrome -Corona Virus-2 (SARS-CoV-2) [2]. This virus is genetically related to other coronaviruses most notably Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). The virus spreads rapidly, and outbreaks can grow at an exponential rate. On 11 March 2020, the novel coronavirus disease outbreak was officially declared a pandemic by WHO after it has been declared a Public Health Emergency of International Concern (PHEIC) on the 30th of January 2020 [3, 4].

Studies from countries affected early in the pandemic showed that about 40% of cases will experience mild disease, 40% will experience moderate disease including pneumonia, 15% of cases will experience severe disease, and 5% of cases will have critical disease [5]. Estimates of the incubation period for COVID-19 range from 1-14 days with 5 days being the most commonly reported incubation period. The crude clinical case fatality ratio is currently over 3%, increasing with age up to approximately 15% or higher in patients over 80 years of age. The morbidity associated with COVID-19 is also very high. Underlying health conditions such as metabolic diseases (obesity, diabetes), cardiovascular diseases (hypertension), respiratory diseases (Chronic Obstructive Respiratory Diseases), immune systems conditions (cancer) and other infections such as HIV/AIDS, TB and malaria confer an increased risk of severe illness and death [6,7].

Laboratories play a critical role in detection of Covid-19 infection in patients and case management, disease surveillance and control, and in provision of accurate health data for national planning and decision making. The timely detection; further characterization of circulating viruses, tracing of disease transmission; appropriate care of patients, which are all essential for the control of COVID-19, requires appropriate public health measures including laboratory based-surveillance [8,9,10,11].

Timely access and geographic availability to COVID-19 diagnostic testing remains a challenge in the WHO African region and could affect ongoing containment measures.

This guide has been developed based on evidence gathered to date to provide a comprehensive and up to date guidance for laboratory testing for COVID-19 in Africa.

It focuses on the roles of the laboratory and is thereby relevant for laboratory professional staff, policy-makers from the relevant ministries and other stakeholders aims to enable them to take appropriate decisions in implementing the required functions of the laboratory to respond to COVID-19 in the context of the WHO African region

II. Objectives of the guide

This guidance document aims to support Member States of the WHO African region in their ongoing efforts to support laboratory surveillance and response to COVID 19. It guides the users on laboratory testing strategy, developing and managing surge capacities, for testing relevant specimens at all levels of the health system and approaches for ensuring laboratory testing sustainability in the context of shortage of supplies.

The document helps to identify suitable methods consistent with maximizing testing reagents, mobilizing human resources and guide implementation of public health measures when testing results are available and when they are not available. Each country needs to define and adapt these strategies considering the local context and what is required for public health COVID-19 response interventions. This document will complement existing WHO guides and tools for response to COVID-19.

III. Target audience

This technical guidance is intended for all professional staff involved on laboratory-based surveillance and response to COVID-19. The target audience could be heads of public health laboratories, laboratory managers, scientists, or technicians in reference laboratories and other public or private laboratories from relevant sectors at all levels of health system. The guidance could be useful for Members of the national coordination committee for COVID-19 including epidemiologists and clinicians working in the field.

Functions of laboratory during the COVID-19

The main functions of laboratory during the COVID-19 pandemic are as follows [7-10]:

- Establishing appropriate, accurate, and sustainable diagnostic testing capacities to respond to public health needs.

- Ensuring surge capacity to process a large volume of specimens to cope with public health response needs.

- Conducting virological monitoring of the pandemic at national, regional and global levels.

- Ensuring timely release of laboratory information for diagnosis and patient care.

- Collecting, analyzing, and reporting laboratory data and linking data with surveillance data to inform public health decision making and response activities.

- Tracking the genetic evolution of COVID-19 and contributing in research and development of vaccines by characterization of viruses.

People to be tested

To be able to detect and treat patients and implement measures to stop transmission, countries should expand the capacities for testing based on the epidemiological information. In this regard and owing to the availability of resources, the following persons should be tested [8,9,12,13]:

- Suspected COVID-19 cases based on established case definition[1];

- Contacts of confirmed cases focusing on those who have developed symptoms or been within 1 meter of the confirmed case;

- Those presenting with atypical pneumonia and influenza-like illness

Some countries are conducting studies to test for SARS-CoV-2 antibodies at the population level or in specific targeted groups, such as health workers, close contacts of known cases or within households. If means are available, such tests could be promoted for adapting strategic interventions.

---

[1] *National case definitions should be continually updated based on regular risk assessments as the epidemiological situation changes in the country. National case definitions will be used to identify the suspected COVID-19 cases. In addition, the contacts and the recovered cases will be determined using standard operating procedures for contact tracing.*

Tests to be used

There are several tests that can be used for epidemiological, clinical and research activities for COVID-19 [10,11,14]. Tests are based on either direct or indirect detection of the virus.

- Direct detection of SARS-CoV-2 is the preferred way of detecting SARS-CoV-2 for clinical management and real-time reverse-transcription polymerase chain reaction (rRT-PCR) is the gold standard. The scope of methods available for detection of COVID-19 infection are outlined below:

  - Nucleic acid testing routine confirmation of COVID-19 cases is based on detection of unique sequences of virus Ribonucleic acid (RNA) by Nucleic acid amplification tests (NAAT) such as real-time reverse-transcription polymerase chain reaction.

  - GeneXpert and other automated platforms are currently available and can contribute significantly to decentralization of COVID-19 laboratory confirmation.

- Direct antigen detection. The sensitivity of these tests can vary from 34% to 80%.

- Antibody detection assays (serological testing) indirectly detect infection and are usually in the format of a Rapid diagnostic tests (RDTs) or Enzyme Linked Immunosorbent Assay (ELISA). Antibody detection assays can have low sensitivity and their use should be guided by the purpose of testing. These types of tests can support investigation of an ongoing outbreak and retrospective assessment of the attack rate or extent of an outbreak. Such tests cannot diagnose acute infection which is required for better treatment. Antibody detection assays are being considered by some countries in the region, however these tests need to be further assessed before wide-spread roll out. Once the studies are conclusive, RDTs could be useful for screening contacts or suspected cases in hard to reach areas.

- Viral sequencing can be used to provide confirmation of the presence of the virus. Regular sequencing of a percentage of specimens from clinical cases can be useful to monitor for viral genome mutations that might affect the performance of medical countermeasures, including diagnostic tests. Virus whole genome sequencing can also inform molecular epidemiology studies.

- Viral culture is not recommended as a routine diagnostic procedure.

Selection approaches for diagnostic tests

Since the discovery of SARS-CoV-2 many commercial and in-house diagnostic testing reagents have been developed and used in the region [15]. Many molecular assays are currently being validated by partner laboratories and Foundation for Innovative New Diagnostics (FIND) SARS_CoV-2 Diagnostic Pipeline [16].

Although, nucleic acid testing (PCR) for SARS-CoV-2 is the gold standard for testing, it is relatively costly, time consuming and labour intensive and may not be suitable in some settings, particularly in the African region where laboratory systems are often weak. Reagents for automated nucleic acid testing platforms are becoming increasingly available enabling higher throughput and shorter turn-around times for tests with some platforms, but lower through put with others.

Consequently, a number of immunodiagnostic tests for COVID-19 have been developed to provide a cost and time effective methodology for detection of COVID-19 infection.

This has meant manufacturers from around the world are inundating the market-place with easy-to-use immunodiagnostic tests that either detect viral antigens (viral proteins) or antibodies produced following infection with SARS-COV-2 virus. Detection of either of the antigens or antibodies can be performed using a Rapid Diagnostic Test (RDT) or enzyme-linked immunosorbent assay (ELISA) [10,11,14].

As described by Kosack et al. (2017), it is important to examine properly the following steps to select any kit [17]:

- Identify the purpose of the test such as confirmation of suspected cases during the outbreak response or case management outcomes,

- identify the existing manufactures and their requirements if the technological requirements are aligned with the national needs and protocols,

- examine if the test has been approved at global, regional, or national level specifically the national committee for COVID-19 or a national regulatory authority,

- assess the test's performance and accuracy at national level and,

- ensure quality assurance of the kit to better design the algorithms for diagnostics.

Types of specimens to collect for testing

A risk assessment should be carried out for any specimen collection procedures to ensure that appropriate PPE is selected, and procedures are in place and followed [18].

Respiratory samples have the greatest yield of virus. However, the virus can be detected in other specimens, including stool and blood [10].

Respiratory material should be collected from [10,11]:

- upper respiratory specimens: nasopharyngeal or oropharyngeal swab or wash in ambulatory patients
- and/or lower respiratory specimens: sputum (if produced) and/or endotracheal aspirate or bronchoalveolar lavage in patients with more severe respiratory disease.

In case of deceased individuals, consider performing a respiratory swab if possible, as soon after death as possible, and collection of autopsy material including lung tissue.

It is critical to strictly adhere to infection prevention and control procedures, particularly during the collection of oropharyngeal, nasopharyngeal and lower respiratory tract specimens as there is a high risk a patient generating aerosols [10,11].

Preparation, storage, and transportation of collected samples

Ensure that adequate standard operating procedures (SOPs) are in use and that staff are trained for appropriate specimen collection, storage, packaging, and transport and the required biosafety measures. All specimens collected for laboratory investigations should be regarded as potentially infectious.

It is essential to ensure that health care workers who collect specimens adhere rigorously to infection prevention and control guidelines. In this regard, the following recommendations should be implemented during the preparation, storage and transportation of specimens [10,11,12,14,19,20]:

- **Specimens should be correctly labelled and accompanied by a diagnostic request form.**

- **Specimens for virus detection** should reach the laboratory as soon as possible after collection.

- **Correct handling of specimens during storage and transportation** is essential. Specimens that can be delivered promptly (within 48h) to the laboratory can be stored and shipped at 2-8°C. When there is likely to be a delay in specimens reaching the laboratory, the use of appropriate viral transport medium is strongly recommended.

- **Specimens may be frozen to - 20°C or ideally -70°C and shipped on dry ice** if further delays are expected. It is important to avoid repeated freezing and thawing of specimens.

- **Transport of specimens within national borders should comply with applicable national regulations.** International transport of potentially COVID-19 virus containing samples should follow the UN Model Regulations, and any other applicable regulations depending on the mode of transport being used. Patient specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance, Category B".

- **Once specimens reach the laboratory, initial processing should take place in a certified Class II biological safety cabinet (BSCII) or primary containment device in a laboratory equivalent to Biosafety Level 2 (BSL-2) [21].**

- **Appropriate disinfectants with proven activity against enveloped viruses should be used** (for example, hypochlorite [bleach](0.1% surfaces, 1% blood, bodily fluids and spills), alcohol (62-71%), 0.5% hydrogen peroxide, quaternary ammonium compounds e.g. cetylpyridinium chloride and phenolic compounds).

> *Note:* WHO has established a shipment mechanism to expedite and cover the costs of the shipment of clinical samples from patients with suspected COVID-19 from the country (for example countries who have no testing capacity and national COVID-19 laboratories with limited experience on COVID-19 virus testing) to one of the WHO reference laboratories providing confirmatory molecular testing for COVID-19 (first five positives and the first ten negative COVID-19 samples) [22,23].

Timing of the specimen collection for testing

COVID-19 is a new virus, therefore, very little data is available on the timing and strength of protective immunity following infection in different population groups. The timing and strength of immune response to any pathogen is unique to an individual and can be influenced by many factors such as age, nutritional status, severity of disease, and certain conditions such as HIV/AIDS, cancer and medications that suppress immune system. The timing of immune responses and likely positivity in a range of specimens over time are illustrated in Figure 1 [24].

Figure 1: Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset. (From: Nandini Sethuraman et al., 2020, JAMA doi:10.1001/jama.2020.8259)
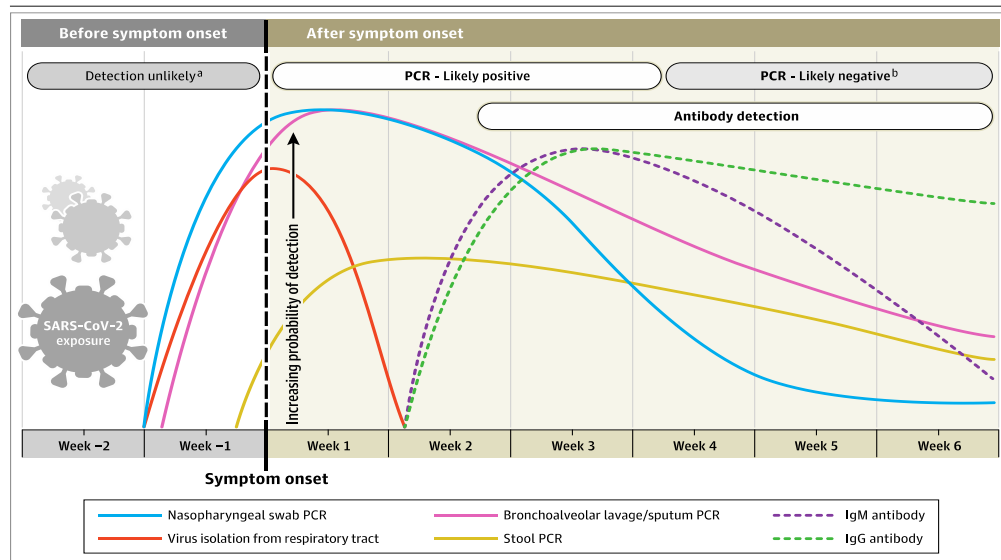
Estimated time intervals and rates of viral detection are based on data from several published reports. Because of variability in values among studies, estimated time intervals should be considered approximations and the probability of detection of SARS-CoV-2 infection is presented qualitatively. SARS-CoV-2 indicates severe acute respiratory syndrome coronavirus 2; PCR, polymerase chain reaction.

[a] Detection only occurs if patients are followed up proactively from the time of exposure.

[b] More likely to register a negative than a positive result by PCR of a nasopharyngeal swab.

Viral antigens and nucleic acid can be detected soon after infection and for as long as the virus is replicating in cells. Since antibodies to COVID-19 are not produced immediately after infection, antibody tests are best performed 7 or more days post symptom onset [10,11,14]:

- IgM antibodies are produced first, and IgM indicates an active, acute infection and this antibody types declines over time.

- IgG is produced a little later, these antibodies are called convalescent antibodies and last for a longer time.

Interpretations of results

An individual will be considered as a laboratory-confirmed COVID-19 positive based on the national standard operating procedures delineating requirements/limits for tests to be positive in alignment with recognized standards. However, the national senior laboratory professional may adapt the interpretations of the result for better implementation public health control measures considering the national context and the epidemiological situation. Furthermore, a "no regrets" policy approach could be used to classify cases using all available information including clinical picture, laboratory test results, epidemiological information and medical imaging results; and based on circumstances. Interpretation of different tests by stage of infection is summarized below.

Table 1: Interpretation of test by stage of infection based on Figure 1.

Stage of infection Exposure to infection = Day-14	PCR	Antibody RDT		Interpretation
		IgM*	IgG*	
Post Exposure – Day -14 to -7	-	-	-	Virus not detectable
Post exposure – Days -7 to 0	+/-	-	-	Window period, virus may be detectable
Symptom onset – Day 0	+	-	-	Early stage of infection
Peak viral replication Day 0 to 7	+	+/-	+/-	Active phase of infection
Day 8 to 14	+	+/-	+/-	Beginning of convalescence
Day 15 - 21	+/-	+	+	Stage of convalescence
Post day 21	-	+	+	Recovery stage of infection
	-	-	+	Patient has had past infection or has recovered from infection

* Timing of rise and fall of immune responses is variable depending on the individual.

For laboratory-confirmed cases, two negative specimens at least 24 hours apart indicate recovery from infection. Based on initial data, this is estimated to be 14 or more days after resolution of symptoms. Laboratories should follow national reporting requirements.

In general, all test results, positive or negative, should be immediately reported to national authorities. Laboratories are urged to seek confirmation of any unusual results by an international reference laboratory within or outside the region [10,11].

Laboratory testing strategies
(a). Testing strategies based on scale of transmission in a selected area/district

WHO has defined four transmission scenarios for COVID-19 [10-13, 25]:

- No cases but ongoing surveillance,

- A few largely unconnected cases, imported or locally detected with infection transmission risk limited to contacts of cases (Sporadic Cases),

- Multiple cases with local transmission, related in time, geographic location or common exposure and infection transmission risk limited to members of the cluster (Cluster of community transmission),

- Widespread and unconnected clusters of cases across the given area or country with ongoing local transmission and infection transmission risk is the same for any exposed person (widespread community transmission).

As the COVID-19 outbreak evolves, countries may experience one or all of these scenarios at any level of the health system and should adjust and tailor their approach to testing based on the local context and capacity to test. In each scenario, testing should be performed for all the cases who are symptomatic of COVID-19. Depending on the intensity of transmission and laboratory testing and surge capacity, it may be necessary to consider prioritizing who gets tested according to public health objectives.

(i) **Sporadic cases:** This scenario envisages a situation in countries or districts where containment measures can still work well if cases are rapidly identified and contained. You should consider testing the following:

- Test all individuals meeting the suspected case definition.
- Test all new arrivals in a particular area (if the Points of Entry are open) if it is aligned with the national testing policy.
- Test all contacts.
- Test all recovered cases based on the national protocols.

In this scenario, the rRT-PCR will be used. For the new arrivals at PoEs, the direct antigen detection RDT could be used as alternative based on the sensitivity of the test. However, it is a good idea to collect naso/oropharyngeal swabs for storage and testing at a later time.

(ii). **Clusters of cases of resulting from community transmission:** This scenario envisages a situation in countries or districts where containment measures are insufficient to respond to sporadic and localized transmission. The test could consider the following:

- Test all individuals meeting the suspected case definition.

- Test all new arrivals (if the PoE are open), if there are still sporadic cases or limited clusters of cases. This needs to be considered based on the national testing strategy as well as the availability of tests.

- Test all contacts with more focus on those with morbidity associated with COVID-19. However, it is crucial to consider specifically those who are symptomatic.

- Test all recovered cases based on the national protocols

In this scenario, the rRT-PCR will be used. Therefore, for the new arrivals at PoEs and the contacts, the direct antigen detection could be used as alternative based on the sensitivity. However, it is proposed that all symptomatic RDT negative and all RDT positive have specimens collected for confirmation using molecular method.

(iii). **Widespread community transmission:** This scenario envisages a situation in countries or districts where containment measures have failed and there is widespread transmission. In this regard, testing using rRT-PCR could be further dedicated for the following cases:

- At least one suspected case for an identified cluster of potential COVID-19 etiology.
- High risk and vulnerable populations to COVID-19
- Health workers including emergency services and non-clinical staff
- Communities in closed settings (e.g. schools, long term living facilities, prisons, hospitals) ensure containment measures.
- High risk contacts and quarantined persons

The use of point-of-care immunodiagnostic tests for COVID-19 will be promoted for patient triage as much as possible if testing is considered necessary and sensitivity of tests is within an acceptable range.

The above scenarios are dynamic and as the pandemic in the Region evolves countries may experience one or all of these scenarios at any level of the health system and should adjust and tailor their approach to testing based on the local epidemic situation, local context and capacity as well as any other relevant factors.

Depending on the intensity of transmission i.e. the number of cases and laboratory testing and surge capacity, it may be necessary to prioritize who gets tested in agreement with national public health objectives. For example, priority should be given to the detection and protection of vulnerable patients and health care workers.

(b) Testing strategies based on health systems capacity, resourcing and context

Currently, countries in the region are at different stages of national and subnational laboratory capacity in terms of equipment, human resources, stockpiles of required reagents and supplies.

In addition, the mechanism for procurement of reagents is still challenging due to global shortages as well as lack of domestic funds to maintain laboratory testing capacity in line with the national needs. Some countries rely on support from partners for running of COVID-19 laboratory activities. In addition, if the scale of transmission in a district is considered, the decision to test could also be adapted based on health systems capacity, resources and context (High-capacity settings, mid-capacity settings, low-capacity settings and humanitarian settings). In this regard, the approach to COVID-19 testing in each country may change due to many factors. However, it is crucial to expand the capacity to test individuals so as to maximizes the effect of public health measures. Furthermore, countries are in the process of easing the lockdown measures and the risk of re-introduction and re-emergence of the disease will continue along with the needs to sustainably mitigate transmission as the   virus circulates between and within countries. Therefore, selection criteria for testing needs to be established jointly between epidemiologists, clinicians and laboratory professional to ensure adequate laboratory testing is conducted. Countries with limited resources and capacity are specifically requested to consider prioritizing testing. [11,12,13, 25].

A projection on the reagents and supplies needed could be developed using modelling on how the COVID-19 pandemic could unfold with proposed different potential scenarios.

This study could be done in collaboration with epidemiologists with the required expertise on modelling. This approach will enable decisions on the prioritization approaches for the different scenarios without compromising the public health control measures. Therefore, it is encouraged to use reliable methods for determining suspected cases and no regret policy could be implemented for determining probable cases without systematically conducting laboratory testing specifically once in the area there are already evidence of community transmission.

An appropriate algorithm should be developed to classify cases based on epidemiological, clinical and laboratory information in line with the methods of diagnosis. It may not be necessary to test all the contacts or suspected cases linked with confirmed cases if cases are too many and the presenting symptoms in the area are clearly recognized. In such instances, management could continue presupposing positivity, and specimens kept for testing in the future when capacity has improved for confirmation. This way, public health decisions to control the COVID-19 pandemic are not compromised. Promotion of the use of rapid diagnostic tests could be encouraged complemented by good interpretation of results.

The standard operating procedures need to be regularly updated to align with the selected approaches to be implemented by sections of the emergency committee in charge of epidemiological surveillance, case management and laboratory diagnostics. These SOPs should consider not only the resources available but also the status of the transmission of the disease in each district to better formulate a tailored and rational approach to testing. Stakeholders are encouraged to mobilize resources to make available laboratory reagents and supplies to ensure adequate testing capacities. Therefore, better planning and projection is required to avoid interruptions to testing due to lack of reagents.

As there is increased molecular testing for COVID-19 globally and regionally, shortages of molecular testing reagents and supplies for COVID-19 have occurred. This issue has an impact in the African region, especially in low- and middle-income countries. In this regard, a combination of information from different sources needs to be regularly examined to allow the adaptation of testing strategy without interfering in the national health objectives. Each country could decide on the approach to be adapted and testing must be rationalized in areas with community transmission and where testing capacity cannot meet needs. The use of different laboratory methods could be promoted and adjusted to fit with national priorities taking into account the advantage and limitation of the different kits.

Some countries are also conducting studies to test for SARS-CoV-2 antibodies at the population level or in specific targeted groups, such as health workers, close contacts of known cases, or within households. If means are available, such tests could be promoted for adopting these types of strategic interventions [26].

Approaches for decentralization of the laboratory testing

Expanding the ability of health systems to provide high quality supportive care to patients with COVID-19 is necessary to save lives. Countries are decentralizing case management and epidemiological surveillance activities in the context of the Integrated Disease Surveillance and Response (IDSR) to the districts.

As stipulated in the Joint External Evaluation (JEE) tool, it is crucial to ensure use of the nationwide laboratory network system for timely detection and characterization of pathogens causing epidemic or pandemic disease using regional and global reference laboratory networks [12,27].

A national system should be in place to transport specimens to COVID-19 testing laboratories for confirmation from 100% of intermediate level/districts within the country. In addition, countries could expand human resource and laboratory capacities by engaging other relevant sectors such as academic institutions, veterinary services and private health services/laboratories. It is also encouraged to consider the possibility to use mobile laboratories in inaccessible areas. Furthermore, all existing platforms and testing methods from different vertical programmes could also be repurposed to increase testing capacity at all levels of the health system. An operation plan should be rapidly developed and implemented to enhance workforce capacities through online training sessions, development of videos for training on key laboratory methods, in-service laboratory training and attachments to national reference laboratories.

The decentralization initiative for expansive testing within the health system delivery area is needed to avoid overwhelming of national reference laboratories which could affect performance due to several factors such as laboratory staff are exhausted and working hours need to be reduced; the number of incoming samples exceeds the capacity for safe pretesting storage; the critical staff become infected or are otherwise unable to perform their duties (e.g. being in quarantine) and the laboratory instruments can no longer be serviced or properly maintained.

Approaches for sustainability of laboratory testing

Fostering partnership by bringing together all stakeholders both traditional and new partners and donors through active engagement of national stakeholders is required to ensure effective and sustainable interventions. Supportive supervisory visits should be conducted for identifying major gaps and providing short term and midterm solutions for the improvement of performance of all laboratories involved in COVID-19 diagnosis. Collaboration among countries using existing regional and national laboratory networks in various programmes need to be further promoted building on the successful lessons learnt from the Ebola and other outbreak in Africa [28].

Innovation, Research and Development on laboratory for COVID-19 response

Laboratory plays a critical role in accelerating the research and development of vaccines, therapeutics, diagnostics and other innovations. Existing networks of reference laboratories and academic institutions in the region with support from the World Health Organisation (WHO), Africa Centre for Disease Control and Prevention (AfCDC) and other technical partners continues to promote operational

research to end this pandemic and also to identify the most effective strategic approaches for adequate preparedness for the next pandemic [8,9].

Sequencing of the viruses circulating in Africa is required to understand the following about COVID-19: a) spread of the disease, b) genetic make-up of viruses circulating in the Region, c) type of transmission whether is localized or it is an importation through molecular epidemiology studies. This data will assist public health decision makes in identifying steps to be taken to stop transmission such as usage of vaccine if available. Regional and sub-regional reference laboratories will be continually supported to contribute to the regional and global genetic characterization of COVID-19. Additionally, a percentage of positive cases should be sequenced to monitor mutations that might affect efficacy of diagnostics and development of COVID-19 vaccines.

There is a need to support the development and the validation of the new rapid diagnostic tests for COVID-19 as well in-house reagents. A regional system should be promoted to ensure the dissemination of regional products to other laboratories for enhancing testing capacities. In this regard, comparative studies of available molecular and serological assays should be encouraged.

Countries should promote innovations that can rapidly support the laboratory services for example the use of drones to shuttle medical supplies and carry samples from suspected coronavirus patients to laboratories in Ghana, allowing the country to quickly monitor the spread of COVID-19.

Monitoring and evaluation

Countries should track the quantities and results of testing using key testing performance indicators and consider reporting to WHO. WHO will continue to monitor the laboratory performance for surveillance and response to COVID-19 using an electronic COVID-19 Laboratory Performance Monitoring System (see annex) and from the WHO External Quality Assessment Programme. Corrective actions will be conducted to maintain reliable testing capacity. Furthermore, networks of reference laboratories will be enhanced for sharing experiences on lessons learnt and best practices.

Regional documentations will be produced and disseminated with the aim of sharing information on strengths and weaknesses for harmonized technical guidance based on specific countries' need. In addition, the laboratory based-surveillance on COVID-19 will contribute considerably in monitoring the course of the pandemic considering the geographical

spread, trend, transmissibility, seriousness and impact within the country, region and the world. Regional database will be developed, regularly analysed and results made available for timely decision making [8,9].

Annexe 1: COVID-19 Laboratory Performance Monitoring System

COVID-19 Laboratory Performance Monitoring System	
Description	**Comments or YES/NO**
General Information	
Name of the Country:	
Name of the Institute/Laboratory/Hospital:	
Location (address):	
Head of lab and contact details	
Laboratory Code	
Person filling the form and contact details (email):	
Type of Tests	
Nucleic acid test used for COVID-19 in laboratory:	
Other tests used nationally (Ab or Ag RDT, please indicate brand)	
Date EQA panel for testing COVID-19 received.	
Date EQA panel results returned.	
Specimen Data	
Number of specimens received weekly	
Number of specimens processed weekly	
Number of SARS-CoV-2 positive specimens	
Number of SARS-CoV-2 negative specimens	
Number of SARS-CoV-2 pending results	
Number of SARS-CoV-2 inconclusive specimen	
Number of SARS-CoV-2 rejected specimen	
Number of SARS-CoV-2 specimens referred to national laboratory	
Number of SARS-CoV-2 specimens referred to international laboratory	
Reagents and supplies	
Number of patient tests do have remaining in the lab at time of completing the form	
Is your lab conducting Research and development for new tests	

References

1. World Health Organization (2020), Pneumonia of unknown cause – China, Available from: < https://www.who.int/csr/don/05-january-2020-pneumonia-of-unkown-cause-china/en/>. [Accessed: 30 April 2020].

2. World Health Organization (2020), Naming the coronavirus disease (COVID-19) and the virus that causes it, Available from: < https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it>. [Accessed: 30 April 2020].

3. World Health Organization (2020), Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), Available from: < https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)>. [Accessed: 30 April 2020].

4. World Health Organization (2020), WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020, Available from: < https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>. [Accessed: 30 April 2020].

5. World Health Organization (2020), COVID-19 Strategy update, Available from: < https://www.who.int/docs/default-source/coronaviruse/covid-strategy-update-14april2020.pdf?sfvrsn=29da3ba0_19>. [Accessed: 30 April 2020].

6. Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected, Interim guidance, 13 March 2020, World Health Organization.

7. Home care for patients with COVID-19 presenting with mild symptoms and management of their contacts, Interim guidance, 17 March 2020, World Health Organization.

8. Guide for establishing a National Health Laboratory System, WHO Regional Office for Africa, 2014.

9. Guide for National Public Health Laboratory Networking to strengthen Integrated Disease Surveillance and Response (IDSR), September 2008, WHO/AFRO.

10. Laboratory testing for coronavirus disease (COVID-19) in suspected human cases, Interim guidance, 19 March 2020, World Health Organization

11. Laboratory testing strategy recommendations for COVID-19 Interim guidance 22 March 2020, World Health Organization

12. Annex 11 on Coronavirus disease 2019 (COVID 19) pandemic, 3rd Edition of the Integrated Disease Surveillance and Response [updated in May 2020], WHO Regional Office for Africa, 2019.

13. Considerations in the investigation of cases and clusters of COVID-19, Interim guidance, 13 March 2020, World Health Organization

14. Advice on the use of point-of-care immunodiagnostic tests for COVID-19, Scientific Brief, 8 April 2020, 4. World Health Organization

15. World Health Organization (2020), Summary table of available protocols in this document, Available from: <https://www.who.int/docs/default-source/coronaviruse/whoinhouseassays.pdf?sfvrsn=de3a76aa_2&download=true, [Accessed: 6 May 2020].

16. FIND, SARS-COV-2 diagnostic pipeline, Available from:< https://www.finddx.org/covid-19/pipeline/, [Accessed: 6 May 2020].

17. Kosack, CS et al. (2017), 'A guide to aid the selection of diagnostic tests', Bulletin of the World Health Organization 2017;95:639-645. doi: http://dx.doi.org/10.2471/BLT.16.187468.

18. World Health Organization (2020), Health workers exposure risk assessment and management in the context of COVID-19 virus, Interim guidance, 4 March 2020, Available from: < https://apps.who.int/iris/bitstream/handle/10665/331340/WHO-2019-nCov-HCW_risk_assessment-2020.1-eng.pdf?sequence=1&isAllowed=y>. [Accessed: 7 May 2020].

19. JOB AIDS for collection, storage and transport of specimens for laboratory confirmation of Middle East respiratory syndrome coronavirus (MERS-CoV), WHO Regional Office for Africa, 2013.

20. Guidance on regulations for the transport of infectious substances 2019–2020, WHO/WHE/CPI/2019.20, World Health Organization, 2019.

21. Laboratory biosafety guidance related to coronavirus disease (COVID-19), Interim guidance, 19 March 2020, World Health Organisation.

22. Guidance for laboratories shipping specimens to WHO reference laboratories that provide confirmatory testing for COVID-19 virus, Interim guidance, 31 March 2020, World Health Organization.

23. World Health Organisation (2020), WHO COVID-19 Reference Laboratory Network, Available from :< https://www.who.int/docs/default-source/coronaviruse/who-reference-laboratories-providing-confirmatory-testing-for-covid-19.pdf?sfvrsn=a03a01e6_12&download=true>, [Accessed: 7 May 2020].

24. Sethuraman, N et al. (2020), 'Interpreting Diagnostic Tests for SARS-CoV-2', 2020 American Medical Association, JAMA Published online May 6, 2020, doi:10.1001/jama.2020.8259.

25. COVID-19 Strategic Response Plan for the WHO African Region, Version 23 April 2020.

26. World Health Organization (2020), Immunity passports in the context of COVID-19, Available from: < https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19>. [Accessed: 30 April 2020].

27. Joint External Evaluation tool, International Health Regulations (2005), 2nd edition, World Health Organization, 2016.

28. Ebola virus outbreak in west Africa: update and lessons learnt, Sixty-fourth session Regional Committee for Africa, AFR/RC64//9, 1 August 2014, World Health Organisation for Africa.

Acknowledgements

This is not an official publication of the World Health Organization. Correspondence on this publication may be directed to:

Dr Ali Ahmed Yahaya
Antimicrobial Resistance (AMR) Team Lead
WHO Assistant Regional Director (ARD) cluster
WHO Regional Office for Africa
P O Box. 06 Cité du Djoué, Brazzaville, Congo
Email: aliahmedy@who.int