

REPUBLIC OF KENYA



MINISTRY OF HEALTH

**TARGETED TESTING STRATEGY
FOR CORONA VIRUS DISEASE 2019 (COVID-19) IN KENYA**

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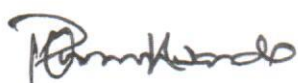
1 Foreword

Diagnostic testing to identify individuals infected with Severe Acute Respiratory Syndrome coronavirus-2 (SARS-CoV-2) plays an important role in the control of the COVID-19 pandemic. It enables diagnosis of cases to guide clinical management, facilitates identification of cases for isolation to reduce transmission, and provides estimates of prevalence at the population level to guide intervention implementation and resource planning

First, efficient and timely testing is a vital prerequisite for early identification and reporting of COVID-19. Coupled with adequate contact tracing, isolation (of cases) and quarantine of contacts, this is critical in preventing transmission and slowing down the spread of SARS-CoV-2.

There are several testing methods for SARS-CoV-2. Molecular tests detect the viral RNA in pharyngeal swabs (nasal or oral), with varied range of the manual and automated machine platforms available in the testing laboratories. Serological tests detecting either viral antigens in patient's blood or patient's antibodies against SARSCoV-2 are also commercially available. However, the accuracy of antigen and antibody detecting tests as clinical diagnostic tools has not been well established and require further studies. The appropriate application of these tests varies depending on the goal of testing and stage of disease. For the identification of active SARS-CoV-2 infection, RT-PCR tests are the current reference diagnostic standard in use in Kenya while continuing to evaluate immunodiagnostic assays for future use in the identification of exposed individuals.

This strategy aims at defining the most appropriate approach to achieve the current testing needs of the country, bearing in mind the global supply chain challenges in laboratory testing kits, reagents and supplies. The strategy leverages on maximizing the testing capacity of all the available platforms combined with the expertise available in different labs in the country while ensuring testing quality remains high across sites.



Dr. Patrick Amoth
Ag. Director General for Health

2 Acknowledgement

Many individuals and institutions at their different levels of health care system have participated in the process of developing this strategy. The Ministry of Health is grateful to all of them for their concerted effort to develop the strategy which will go a long way in guiding the way country moves forward with laboratory testing for SARS-CoV- 2 which in turn impacts significantly on the National response to COVID-19.

The Ministry of Health acknowledges the role the played by the Directorate of Public Health and Department of Laboratory services for spearheading the developing of the strategy to address the COVID-19 testing challenges that the country has faced since the advent of the pandemic. Appreciation goes to Professor Omu Anzalla, Professor Matilu Mwau, Dr. Bernard Ogutu, Dr John Ndemi Kiiru, Dr. Loice Achieng, Dr. Nelly Yatich, Mr Mamo Umro for their valuable contributions towards the development of this strategy.

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Dr. Francis Kuria
Ag. Director, Directorate of Public Health



Dr. Simon K. Kibias
Ag Director, Directorate of
Standards, Quality Assurance and
Regulations

3 Introduction

The Coronavirus 2019 (COVID-19) pandemic was first reported on 31st December 2019 in Wuhan City, Hubei Province, China. By 13th June 2020, **7,625,883** cases and **425,931 deaths** had been reported globally. Given the rapid geographical spread of the disease, the World Health Organization (WHO) declared it as a pandemic on 11th March 2020 and recommended that all countries heighten their preparedness and response interventions.

Kenya had reported **Six thousand, three hundred and sixty-six (6366)** confirmed cases of COVID-19 including **One hundred and forty-eight (148)** deaths (CFR 2.3%) by 30th June 2020. The index case was confirmed on 13th March 2020. A total of 8,091 contacts have been traced and follow up is ongoing. In response to the outbreak, the Government has put in place multiple interventions to contain the outbreak. These interventions include promotion of personal hygiene including handwashing and use of sanitizers, social/physical distancing strategies such as closure of learning institutions and places of worship, ban on international passenger flights and cancellation of large gatherings to further reduce the spread of COVID 19 in the country. Additionally, restriction of movement in and out of five high risk counties namely Nairobi, Mombasa, Kilifi, Kwale and Mandera was enforced.

Since the beginning of the outbreak, WHO has emphasized the importance of testing. During the early stages of the pandemic, the target of testing in Kenya was persons with symptoms of COVID-19 and international travelers returning from COVID 19 affected countries. However, with the evidence of established local transmission in the country (57% of current confirmed cases) new testing and management approaches have been implemented to break transmission chains in the community. This is core in any public health approach and is hinged on rigorous tracing and testing of contacts and isolation of positive persons.

Mass or large-scale testing of either the entire population or a large proportion of the same would allow for more accurate determination of the true population prevalence and enable isolation of confirmed cases to reduce transmission. However, this is not feasible particularly in low middle-income countries (LMICs) due to the cost, technology and expertise required to conduct the current gold standard test of RT-PCR on manual or high throughput automated platforms. Further, the increase in global demand for equipment, test reagents and supplies has resulted in scarcity making it particularly difficult for LMICs to secure necessary commodities. It is therefore important that each country chooses the most appropriate testing strategy taking in to account the available resources.

In the recent weeks, Kenya has increased her testing capacity resulting in identifying more numbers of positive cases of COVID-19. **Forty-one (41)** out of forty-seven (47) counties are now reporting the disease with established community transmission in several (5) of the counties. Despite the efforts made, the scale up of testing has been hampered by acute shortages of testing

reagents. It is for this reason that the Ministry of Health has chosen to review its testing strategy in order to match supply of reagents, supplies and testing capacity. The strategy will inform timely, appropriate and effective public health response to break the transmission of the ongoing COVID-19 pandemic.

4 Aim

The aim of this strategy is to define clear priorities for testing for SARS-CoV-2 in Kenya in order to advise on resource planning and effective strategies to interrupt COVID-19 transmission in the country. The strategy therefore aims at defining:

- a. Reasons for testing
- b. Targeted population for testing
- c. Requirements to achieve the desired level of testing

Special considerations for testing

5 Situation Analysis

As part of the Global Strategic Preparedness and Response Plan, the WHO developed testing strategy recommendations for member states¹. One of the integral parts of this strategy is laboratory testing to increase country level of preparedness and response capacity in order to identify, manage, and care for new cases of COVID-19.

As a ministry, a testing protocol was developed with priorities for targeted testing as follows:

- a) High-Risk/High Priority groups
 - i. All individuals meeting current MOH case definition (see Appendix I)
 - ii. All contacts of confirmed cases at conclusion of quarantine period, as per MOH guidance
 - iii. Sentinel health facilities conducting ILI and SARI surveillance in counties without evidence of ongoing transmission, in order to provide information on the true geographic scope of COVID-19 transmission in Kenya
 - iv. All frontline health workers working as rapid response teams, working in quarantine centers, isolation facilities and testing laboratories. *A frontline health care worker includes health care professionals, auxiliary health workers (e.g. cleaning and laundry personnel, clerks, phlebotomists, cleaners, admission/reception clerks, patient transporters, catering staff etc.) who by their nature of work puts them at risk of contracting COVID-19.*

¹ See reference 1

- v. All hotel/institution workers where international travelers and high-risk contacts were mandatorily quarantined
- vi. Truck drivers and airline crew, especially those crossing international boundaries and those who seek accommodation/spend nights in areas where there is ongoing community transmission
- vii. Port health and non-health staff working at airports, seaports, ground crossings and check points (points of control)
- viii. In areas of confirmed transmission prioritization of staff at supermarkets, PSV crew, market vendors, security personnel and other individuals with
- ix. Geographic areas, subpopulations or institutions which have reported clustering of cases e.g. Port institutions and airlines, as defined by current epidemiologic data.

b) Health facility based

- i. All patients requiring admission for severe respiratory disease or medical attention for influenza like illness (ILI) at all the 47 county referral hospitals and selected private and faith-based hospitals etc.
- ii. Patients with chronic diseases likely to be complicated by COVID-19 disease e.g. HIV, Diabetes, Hypertension, Renal, cardiac, cancer, TB

c) Community and Population based:

- i. Clusters of severe respiratory illness/deaths identified through ongoing community event-based surveillance
- ii. Clusters identified in the HDSS platforms
- iii. Geographic hotspots as defined through ongoing surveillance, case identification and contact tracing

The testing of the above groups has been hampered by a perennial shortage of reagents that threatens even the prioritization of confirmatory testing of suspected cases. Existing laboratory infrastructure has also not been able to cope with the demand for testing.

6 Laboratory Capacity

A number of laboratories in Kenya have capacity for nucleic acid amplification testing (NAAT) for HIV and other pathogens. In 2019 alone, seven (7) laboratories ran one million seven hundred (1,700,000) viral load tests with relative ease using automated equipment from Abbott and Roche. Currently, SARS-COV-2 testing utilizes this HIV testing infrastructure as well as manual platforms that were installed for surveillance of influenza, viral hemorrhagic fevers,

vaccine preventable diseases and other priority pathogens under integrated disease surveillance (IDSR).

As at June 2020, this existing laboratory capacity could test at least 7,300 samples daily if all manual and automated platforms are utilized and reagents are available. As the country continues to record a rise in number of COVID-19 cases, there is need to continue mobilizing additional testing resources. The use of the Gene X-pert platforms that are spread out in all counties and capable of supporting the response at county level is yet to be realized due lack of the requisite reagents.

As of 8th June 2020, for SARS-COV-2 testing, there are ten Laboratories with high throughput capacity and 15 other laboratories with low throughput. The automated labs are also expected to test for HIV, and the workload for this program has been expanding. The average daily number of HIV tests this year for 260 days (52 weeks) is expected to be 6,925 per day. (this is when both Abbot and Roche equipment are in use at the same time.

Each testing laboratory has skilled human resources, limited only in terms of the numbers required. For the purposes of planning, we can assume that the laboratories are only 50% staffed. At that level of staffing, the existing technologies can be run at 25% of capacity for SARS-COV-2 testing uninterrupted. This therefore allows at least 7,300 to 10,000 SARS CoV 2 tests per day assuming that samples are delivered to the testing laboratories by 10.00 am daily.

Table 1. Laboratories with COVID-19 (SARS-CoV-2) PCR testing capability Across Kenya

Platform	Location (s)	
	County Name	Town
96 well plate Real time PCR machine (Manual Platforms)	Nairobi	NIC (National Influenza Centre)
	Nairobi	KEMRI CDC -Nairobi
	Nairobi	KEMRI VHF
	Kilifi	KEMRI Kilifi
	Kisumu	KEMRI WRP Kisumu
	Kisumu	KEMRI Kisumu CDC HIV Lab
	Kisumu	KEMRI Kisumu Virology
	Kericho	KEMRI WALTER REID Lab Kericho

	Mobile	NPHL Mobile Lab-Namanga
	Mobile	NPHL Mobile Lab-Naivasha
	Wajir	Wajir CRH
	Machakos	Machakos CRH
	Kitale	Kitale County Hospital Laboratory
	Busia	Busia County Referral Hospital Lab
	Malindi	Malindi Sub County Lab
	Nairobi	LANCET
	Nairobi	Aga Khan University Hospital
	Nairobi	Nairobi Hospital
	Nairobi	Nairobi West Hospital
	Nairobi	AMREF
	Nairobi	ILRI
Abbott m2000 (Automated platform)	Uasin Gishu	Eldoret Lab (MTRH/AMPATH)
	Mombasa	Coast Provincial General Hospital
	Kisumu	Kisumu Lab (KEMRI/CDC)
	Busia	Busia Lab (KEMRI) ALUPE
	Nairobi	KEMRI HIV Nairobi
	Nairobi	National HIV Reference Lab
	Kericho	Kericho Lab (Walter Reed)
	Nairobi	KNH
	Nairobi	KDF (Defence Forces Memorial)
Cobas 6800 (Automated)	Mombasa	Coast Provincial General Hospital
	Kericho	Kericho Lab (Walter Reed)

Platform)	Nairobi	Kenyatta National Hospital
Cobas 8800 (Automated platform)	Uasin Gishu	Eldoret Lab (MTRH/AMPATH)
	Nairobi	National HIV Reference Lab
	Kisumu	Kisumu Lab (KEMRI/CDC)
	Busia	Busia Lab (KEMRI) ALUPE
	Nairobi	KEMRI HIV Nairobi
GeneXpert (please list # modules) Closed platform)	Baringo	Kabarnet CRH
	Bomet	Longisa CRH
	Bungoma	Bungoma CRH
	Embu	Embu CRH
	Garissa	Garissa CRH
	Homabay	Homabay CRH
	Isiolo	Isiolo CRH
	Kajiado	Kajiado CRH
	Kericho	KEMRI WRP
	Kilifi	Kilifi CRH
	Kilifi	Malindi DH
	Kirinyaga	Kerugoya CRH
	Kisii	Kisii CRH
	Kisumu	KEMRI CDC Kisian
	Kitui	Kitui CRH
	Kwale	Kwale CRH
	Laikipia	Nanyuki CRH
	Machakos	Machakos CRH

	Makueni	Makueni CRH
	Mandera	Mandera CRH
	Marsabit	Marsabit CRH
	Marsabit	Moyale CRH
	Migori	Migori District Hospital
	Muranga	Murang'a CRH
	Nairobi	Kenyatta National Hospital
	Nairobi	Mama Lucy Kibaki
	Nairobi	Mbagathi DH
	Nairobi	Memorial Hospital
	Nairobi	Coptic Hospital
	Nairobi	Nairobi Hospital
	Nairobi	Lancet laboratories
	Nairobi	Aga Khan Hospital
	Nandi	Kapsabet CRH
	Narok	Narok CRH
	Nyamira	Nyamira CRH
	Nyandarua	Olkalou CRH
	Nyeri	Nyeri CRH
	Siaya	Siaya CRH
	TaitaTaveta	MoiVoi CRH
	TharakaNithi	Chuka CRH
	Trans Nzoia	Kitale CRH
	Turkana	Lodwar CRH
	UasinGishu	Huruma District Hospital
	UasinGishu	Moi Teaching Referral Hospital

	Vihiga	Vihiga CRH
	Wajir	Wajir CRH
	West Pokot	Kapenguria CRH
	Lamu	Lamu County CRH
	Kakamega	Kakamega CRH
	Kericho	Kericho CRH
	Kiambu	Thika CRH
	Kisumu	JOORTH
	Meru	Meru CRH
	Mombasa	Coast CRH
	Busia	Busia CRH
	Nakuru	Nakuru CRH

7 Justification for Focused Targeted testing

Laboratory testing for COVID-19 is critical to tracking the virus, understanding epidemiology, informing case management, and breaking the chain of transmission. Current laboratory testing utilizes molecular methods based on polymerase chain reaction (PCR) assays to detect SARS-CoV-2 RNA.

As the number of individuals testing positive continues to increase, a majority of those testing positive for SARS-CoV02, 88% are asymptomatic at diagnosis; some of them become symptomatic in course of illness and some even die. As asymptomatic, the main strain is on occupation of isolation beds since not much is done in case management except monitoring

On 10th June 2020, the Ministry of Health launched its home-based care protocols that involves caring for positive cases that meet the eligibility criteria for homebased care in a monitored home or community facility environment. This necessitates the development of a diligent surveillance mechanism to identify and trace contacts of those under home-based care and ring-fencing of areas of sporadic out-breaks within communities.

Meantime, the existing capacities for testing have been unable to match the demand for testing. The demand for a balanced cost-effective testing strategy necessitates employment of a well-targeted structured escalation of testing that generates information to be used for evidence-based response activities.

7.1 Why do we test

In the setting of limited resources and with widespread local transmission, testing should focus on the early identification of transmission chains in order to **contain the pandemic** and in order to institute appropriate **mitigation measures** to reduce mortality and protect vulnerable populations. Testing priorities should therefore focus on people who pose a public health risk to the population. The dynamics of disease epidemiology should therefore be the guiding principle to determine testing method to be employed, to who and when. This can change from time to time in terms of shifts in geographical hotspots or the affected population. The Ministry of Health focus is on testing symptomatic individuals, their close contacts and groups posing highest risk of infection spread.

7.2 Priorities for testing

In situations where testing capacity is limited these testing criteria is aimed at informing specific public health interventions 1) ensuring optimal care for hospitalized patients and reducing the risk of healthcare-associated infections, (2) ensuring those at higher risk for severe disease are rapidly identified and triaged, and (3) identifying individuals in communities experiencing high numbers of COVID-19 hospitalizations to decrease community spread and ensure the health of critical infrastructure workers². In order to facilitate such measures including case investigation, contact tracing, hospitalization, home based care focused/localized social-distancing measures, the following people have been targeted and prioritized for testing.

1. All individuals meeting current MOH case definition (see Appendix I), a definitive diagnosis will be required for purposes of focused management
2. All individuals presenting to a health facility with symptoms of upper or lower respiratory tract infection AND who also fulfil the 3 'Suspect criteria' in Appendix 1
3. All health care workers who meet case definition or who present with symptoms of respiratory infection.
4. All health care workers who have been in contact with a COVID-19 patient without appropriate PPE (for symptomatic cases, exposure within 2 days before onset of symptoms and up to 8 days after onset of symptom. For asymptomatic cases 5 days prior to the case testing positive may be considered for potential exposure) for up to a maximum testing of once every 14 days.
5. All close household contacts of confirmed cases³. (for symptomatic cases, exposure within 2 days before onset of symptoms and up to 8 days after onset of symptom. For asymptomatic cases 5 days prior to the case testing positive may be considered for potential exposure)
6. All trans-border and long-distant truck drivers - this group presents a special subgroup at high risk due to their movement across geographical locations. This poses a risk of

² See reference 2

³ See reference 3

translocation of infection from one hotspot region to a non-infected region. Additionally, owing to the existing cross-border travel regulations and requirement for COVID-19 testing, truck drivers testing may be considered a priority group.

7. All prison remandees – any remandee before eventual conviction into a jail sentence poses the risk of infecting a whole prison which is a closed community with potential for catastrophic outcomes
8. In settings with community transmission, contacts who are at risk of developing severe disease and vulnerable populations, who will require hospitalization and advanced care for COVID-19 (to minimize progression to severe disease)

Any other testing should be done within a research or surveillance framework for example Sentinel health facilities conducting ILI and SARI surveillance in counties without evidence of ongoing transmission, in order to provide information on the true geographic scope of COVID-19 transmission in Kenya.

7.3 Mass Testing of Special Groups

In the recent past, the government has undertaken a lot of testing for reasons other than those listed above as part of the public health response. This has included requests from interested groups, travelers, or as part of targeted mass testing campaigns in hot spots basing on epidemiological analysis. For example, as a precondition for reopening of the economy, the government placed COVID-19 testing as a conditionality for re-opening of restaurants and eateries. The utility of this testing as a public health measure has raised several questions in terms of its effectiveness of controlling spread and its cost effectiveness.

As long as hotel workers are not quarantined within the hotel facility where they work, the possibility of contracting the infection from the community they live in immediately after being declared COVID-19 free is very high. On the other hand, the cost effectiveness and feasibility of repeating this test every 14 days as required is uncertain. As such, what hotels like most other economic activities need are stringent hygiene and IPC protocols with clear logs of those that visit these premises for purposes of monitoring and contact tracing. Large hotels should identify a quarantine facility within or close by in case of staff that are exposed or infected and need monitoring but do not require hospitalization.

In the setting of the current supply chain constraints and for the government to manage the budgetary implications of testing any other testing performed outside the public health perspective should be considered on a case by case basis and preferably at a cost to the individual or organization.

7.4 Testing in Geographic hotspots

Mass/random testing of individuals in a perceived or established geographic hotspots is not economically sustainable. The objective is timely identification of positive cases and isolating them to reduce on transmission within the community, and identifying and quarantining their

contacts, especially household contacts to reduce further on transmission. In the community setting therefore, the main effort will be to identify and test symptomatic cases that require hospital care. Once confirmed positive, close household and high-risk contacts will be traced and followed up. If contacts become symptomatic they will be tested and isolated. **There will be need for strong surveillance to note when the number of symptomatic positive cases are increasing in such locations.** If the number of positive cases in a certain locality is noted to be increasing, this will be a sign that asymptomatic cases are even much more, and transmission is intensifying. That specific locality needs to be ring-fenced and isolated until the infection is controlled. Since COVID19 infections has been shown to spread among clusters, spot checks will also be needed to check on spread within hot spots.

7.5 Vulnerable Groups

One other important consideration is the identification of vulnerable individuals within the cluster, including the elderly (>60 years), children below 2 years of age and those with comorbidities that predispose them to a more severe form of disease. These include the following:

- a. Diabetes Mellitus
- b. Cardiovascular disease
- c. Chronic respiratory diseases
- d. Hypertension
- e. Chronic kidney disease
- f. Chronic liver diseases
- g. Immunosuppression – acquired or immunotherapy related
- h. All forms of cancer

Any contact with comorbidities will be monitored closely and if they develop symptoms they shall be tested and isolated within the public health premise of testing.

7.6 Use of Serological tests

Serology based tests shall be used for epidemiology, when they become available and proven to be useful and cost effective. Antigen and IgM assays will not be very useful for acute diagnosis (may be better than nothing in absence of genomic testing), but IgG serology can provide insights into penetration into the population and descriptive epidemiology (time, place, person) and remain a preserve for research. Thoughtful approaches will be required for prioritization of testing - population-based, sentinel groups, available serum banks, etc. The priority is to validate acceptable commercial tests and the algorithms to be used (e.g. sensitive test for screening, followed by supplemental testing with a more specific test).

8 Forecasting And Projection of laboratory Reagents

Forecasting for the right amount and type of reagent is an important aspect of response planning. There is no universally acceptable model for forecasting for reagents and this will largely depend on the testing strategy adopted, the number and location of the testing platforms available and the projected disease pattern within the country.

Laboratory managers will be required to prepare detailed estimates of reagents for each platform based on projected disease burden per county to ensure that all testing platforms perform optimally while maintaining stock levels at 60 days of supply.

8.1 Projections based on transmission dynamics of COVID-19 disease in Kenya

In the worst-case scenario, up to 88% of the Kenyan population could be infected in the period between March 2020 to January 2021. However, with projections using current estimates of transmission within Kenya, 68% of the population will be infected over the period March 2020 to November 2021.

If 68% of the Kenyan population ends up infected, and assuming that 10% - 15% of those will be symptomatic and will therefore need medical attention and testing, then in a population of 48 million people, at least 3,264,000 - 4,896,000 people will need at least two tests each.

Truck drivers and remandees and other special populations will be under constant surveillance, probably receiving tests every two weeks until the strategy evolves. That approach might amount to several hundred thousand tests over one year.

It is therefore safe to assume that on balance, up to 10 million tests will be needed by February 2021. Considering that our current testing capacity of up to 7,300 test a day (about 50,000 tests a week), amounting to 2.6 million tests a year, then the difference (7.4 million tests) will need to be met through other approaches. The approaches needed will include scaling up lab capacity to more county laboratories, encourage pooled testing, and the use of rapid test kits in an algorithm.

8.2 Testing kits supply

There has been a massive challenge in the marketplace to meet the demand for commodities required for the COVID-19 response. This includes the ability to source and acquire Personal Protective Equipment (PPE), Infection prevention and control (IPC) materials and diagnostic commodities. Manufacturers are facing overwhelming demand from the current epicenters of the disease. Manufacturers based in these epicenters are required by their governments to first meet the local needs before exporting any commodities. In any case, all countries are concurrently making orders (often of irrational quantities) resulting in an allocation problem for the production available for countries outside of the current epicenters.

The World Health Organization (WHO) attempted to put together a consortium of funders (Global Fund, UNITAID, World Bank, UNICEF and others) to rally everyone to a common platform that would allow equity in access to commodities as early as March 2020.

The availability of tests from the manufacturers of automated testing platforms is greatly diminished. However, manufacturers of manual testing kits appear to have faced less several challenges and have often managed to close the gap significantly.

Kenya has so far procured at least 130,000 tests since the pandemic began. Of these, 32,000 tests were for automated platforms while 98,000 tests were for manual platforms. Kenya also received some tests as donations from CHAI, Jack Ma Foundation, WHO, World Bank, and Africa CDC. An additional 180,000 automated tests were delivered on 11th June 2020.

The projected immediate need in the next three (3) months ending September 2020 is 730,000 tests. Considering all expected deliveries, the overall gap is 255,472 tests. This status is summarized in Table 1.

Table 2: Current SARS COV 2 tests supply. The immediate gap exceeds 255,000 PCR tests.

Kits	Need	Expected	Date expected	Gap
SD Biosensor	300 kits	28,800	06/08/2020	
Roche	126 kits	24,192	06/11/2020	49,536
Abbott	1875 kits	180,000	06/11/2020	
Sansure	4000 kits	192,000	To be determined	
Total Tests		474,528.00		255,472.00

Support for procurement of kits and laboratory commodities is being mobilized nationally and internationally.

8.3 Test Kit Procurement Plan

This plan is important to prevent stock outs, to better plan commodities and consumables as comprehensively as possible to support COVID-19 pandemic outbreak in the country. Modelling of epidemiology of the disease suggests the disease peak will be in September and therefore the urgent need to plan procurement for the country going forward.

The plan takes into account the current lab outputs in terms of testing. The most realistic approach to this would be based on laboratory capability that takes into consideration (a) machine capacity (b) type of sample extraction method (c) time of sample delivery from the field sites (d) staffing of the laboratory (e) supply and availability of kits.

Based on these approximations, a laboratory with the manual platform was expected to test **200-300** samples a day while that with the automated platform would have an output of **800-1000** tests per day. Using these ranges, the minimum tests that can be done in all laboratories per day are **7, 300** while a maximum of **10, 300** can be performed when each of the 28 laboratories are working at maximum capacity. Using these estimates, it was determined that a total of **1.7M to 2.4M** tests can be performed in the next one year (considering 240 working days in an year (less weekends).

The procurement pipeline and monitoring includes an analysis of split budgets for manual vs automated platforms and this should include total volumes and cost estimates. The forecasting plan also considers purchasing materials for GeneXpert that has not been used in past testing. This platform has now been validated by the FDA. The platform is widely available in most county hospitals and therefore is amenable for use in the response.

Procurement planning should be done in blocks of four months (3 instalments) and the procurement plan should be reviewed before each procurement quota is initiated. This review should consider (a) any changes in testing strategy (b) other validated kits that have entered the market (c) changing price dynamics of kits and reagents since the last procurement quota.

The amount of laboratory and reagents to be procured per year will be purchased in the batches of 40% (first purchase quota) 30% (second purchase quota) and 30% (3rd purchase quota). Each batch will contain reagents and supply with at least a shelf-life of 6 months from the date of delivery (where applicable).

In order to ensure that the country benefits from emerging markets and reducing prices of commodity, it is not advisable to enter into contractual agreements that could curtail flexibility in terms of choice of commodities and the supplier.

Allocation of these commodities will be done equitably across all sites and this will take into consideration, (a) the type of testing platform in a site (b) laboratory testing capability of each site (c) backlog of samples to be tested in each site (c) outstanding commodity stocks in each site. A buffer stock will be held at KEMSA to ensure that stock outs in testing laboratories are avoided.

There is a need to include service contracts for all machines in GoK testing facilities in order to ensure that the results generated in various sites are valid and acceptable.

8.4 Analysis of testing Kits

8.4.1 Supplier of manual testing (30%)

11. SD Biosensor- report of high repeat rates due to a poor internal control. The laboratories must optimize the kits to the test platform available before good results are obtained
12. DaAN (Jack Ma); reports from various laboratories indicate that this is the best performing kits in terms of multiplexing, few repeats and fewer failures.
13. Sansure - Evaluation pending reports from the labs once distributed
14. BGI- failed- gave high false positives. (Lucy to follow up with reports) Thermofisher- (report to follow)
15. Africa CDC – has primer with no enzymes and other reagents and is therefore not suitable due to cost
16. TIB MolBio- (NIC to provide a report)
17. Qiagen (extraction and amplification)- approved from the lab for testing. This kit has been identified as the best manual extraction kit due to compatibility

Notably manual reagents do not come with consumables which hinders testing. All accessories need included in each procurement batch.

8.4.2 DNA/RNA extraction kits for manual platforms

- Based on various sources, the **Qiagen** is best recommended for manual extraction
- The **Promega** is also excellent but has a longer protocol and a need for multiple water baths
- Sigma kit is also good and easy to use for many laboratories
- The **Zymogen** kit is also widely used but it requires the use of a bead beater and magnetic extraction

8.4.3 Supplier automated testing (70%)

- **ROCHE Cobas**- It was noted that delivery of kits from this supplier has led to grounding of the Cobas platforms and this has affected the ability of high through put testing.
- Other platforms are Abbott, Hologic & **GeneXpert**: - - The GeneXpert has now been approved by FDA and the WHO has promised to provide 2500 test for a piloting and optimization in various laboratories. When adding the GeneXpert into the national grid, it is important to note that although automated, accessory reagents such as tips need to be sourced separately.

8.4.4 Kits mix recommendations

For the manual test kits, the brands that have been validated include Da An Gene, TIB MOLBIOL, Sansure, SD Biosensor Standard and Deaou. Other brands will continue being evaluated.

Taking all the above factors into consideration, and if the market circumstances were to improve, then automated tests could take 70% of the share, while manual kits take 30%. It is recommended that validation of upcoming test kits, be accelerated. Point of care tests and ELISA tests are also worthy if significant consideration when new evidence for their use becomes available.

It is anticipated that the use of the GeneXpert platform will soon be validated and available. This will further boost the laboratory capacity especially in the hard-to-reach areas considering that this platform is robust and widely available in most TB-testing sites

8.5 Proposed purchase plans and supply plan monitoring

- If focused targeted testing is adopted, it is estimated that the country will need 1.6M tests for the next financial year. The estimated minimum throughput calculated from the current testing was adjusted to a slightly higher value of 1.7M tests that are required in the next one year. However, for planning purposes, the recommendations are to plan with maximum of 2.4M tests.
 - *To calculate annual lab output, assuming 240 working days in year, country's*
 - *minimum capacity = $7300 \times 240 = 1,752,000$ tests*
 - *Maximum capacity = $10,300 \times 240 = 2,472,000$ tests*
- Assumptions considers 240 days per year that excludes weekend
- Estimated quantities if products should be slightly higher to ensure sufficient kits are in the country
- Procurement planning on quarterly basis and up to three or four orders for the one year (4 quarters- 40%; 30%;30% spilt.)
- Forecasting to include QA/QC and repeat runs.
- Draw down will be done on quarterly basis based on consumption
- A buffer stock for 2 months will be maintained at all times.
- Machines in MoH facilities will need to be assessed for service contracts - Need to review service of equipment's- include budget of servicing and maintenance in forecasting and quantification.

The detailed procurement plan including a detailed itemized budget of the laboratory kits and reagents is attached as **Annex A**.

8.6 Kits Allocation and Commodity management

A committee has been set up with representation from all the major testing laboratories to review the requirements and to determine the quantities that each lab is allocated. Allocations should include certain criteria and buffer stock held in laboratories for unforeseen surges.

- a. Allocation should be based on equitable distribution and confirmation of what lab indicated preferences for testing.
- b. No allocation/budget for specimen referral. WHO have offered to also explore the possibility of securing resources for sample referral for COVID-19 testing.
- c. Buffer stock of kits is required in strategic testing labs. There is need to firm up on where to hold strategic buffers. One of the recommendations is that KEMSA holds buffer the stock. There is need to determine trigger for buffer.
- d. Prioritize County and Sub-County referral hospitals for the distribution of kits.
- e. Opportunity with COVID-19 to strengthen and enhance lab systems.
- f. Committee to include distribution to the commodity management system.
- g. Commodity reporting should include backlog, wastages and repeats going forward. This will help during audit

9 Testing Protocols

9.1 Data collection

For all suspected COVID-19 cases from RRT alerts and SARI surveillance, use of the MOH COVID-19 Case Investigation Form (CIF) (see appendix 2). Investigations conducted under this protocol should be flagged 'Surveillance' in reason for testing. In addition, the CIF will include contact information (phone, address). This will facilitate return of test results, contact tracing and follow up.

9.2 Specimen collection and transportation

Nasopharyngeal (NP) and oropharyngeal (OP) specimen will be collected from ALL individuals identified for targeted COVID-19 laboratory testing. Additionally, blood (serum) may be collected in selected individuals and archived for future surveillance testing. As additional information on COVID-19 emerges other types of specimen may be included if considered important. Existing approved specimen collection and transportation protocols will be used with IATA-approved triple packaging to assure safety during transit. Specimens sent for molecular testing will need to be refrigerated prior to transport and sent on cold packs to maintain cold chain. However, due to the potentially large volume of tests needed in some populations and settings, strengthening of these systems will be required.

9.3 Recommended Specimens

It is important that specimens from cases meeting the COVID-19 case definition are collected in a timely manner and tested for both clinical management and outbreak control. Specimen type will depend on testing methodology, manufacturers test kit recommendations and purpose of testing. Currently recommended specimens for COVID-19 diagnostic testing for acute infection are:

- a. Nasopharyngeal and oral-pharyngeal (see below)
- b. Other specimens include:
 - i. Sputum from the lower respiratory tract if patient can cough it up
 - ii. Bronchoalveolar lavage – BAL (fluid that has been used to wash the lungs)

Ensure SOPs are available, and staff are trained and available for appropriate collection, specimen storage, packaging and transport.

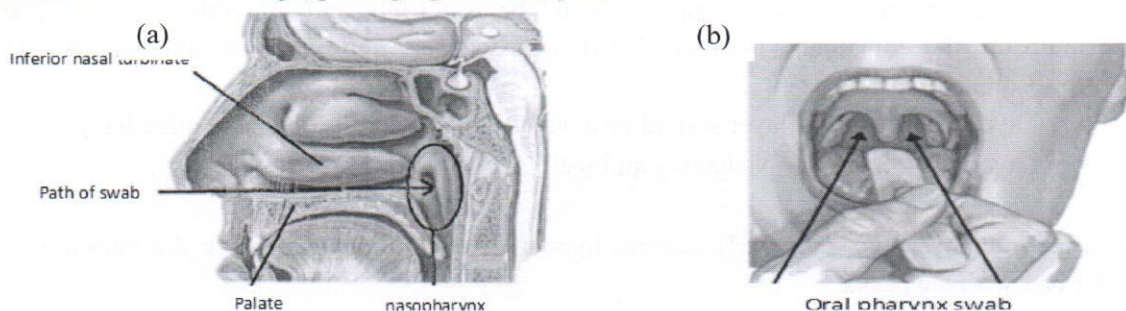


Figure 1: Collection sites for (a) Nasopharyngeal swabs and (b) Oral pharyngeal swabs

9.4 Specimen collection and shipment

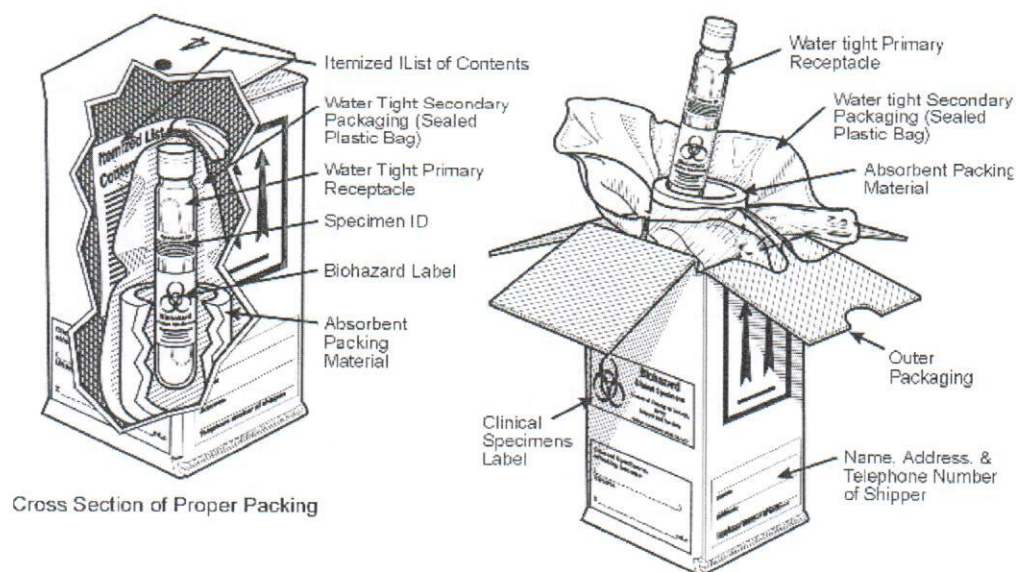
The following measures and procedures need to be adhered to during sample collection and shipment.

- a) **Personal Safety:** All specimens collected for COVID-19 testing should be regarded as potentially infectious. Health care workers (HCW) who collect, handle or transport any clinical specimens should adhere rigorously to the national infection prevention and control (IPC) guidelines for COVID-19 to minimize the possibility of exposure to pathogens. During sample collection, the safety of (HCWs) will be assured by availing appropriate personal protective equipment (PPE) such as gloves, masks, goggles and Tyvek jumpers or disposable lab coats. If the specimen is collected with an aerosol-generating procedure, personnel should wear a particulate respirator such as a certified N95, an EU standard FFP2, or the equivalent. The working environment should be sanitized after sample collection.

- b) Specimen collection: Laboratory results are dependent on proper collection and handling of the specimen. Specimen collection may be done at designated areas outside the laboratory (EOC, facility or other). Refer to specimen collection SOPs for all required materials and collection methods (See Appendix 3). Viral Transport Medium (VTM) should be used in the collection of samples for viral isolation and testing to prevent specimen from drying out as well as bacterial and fungal growth. Appropriate swabs to be used for the nasopharyngeal and the oropharyngeal samples. Specimen should be taken to the laboratory as soon as possible. There should be timely communication between clinical and laboratory staff in order to minimize the risk incurred in handling specimens from patients with possible COVID-19.
- c) Essential documentation: It is important that all specimen and laboratory request forms are properly labelled. The case identification forms should be filled for samples to be tested for COVID-19. Use of electronic data base where available is encouraged (see appendix 2).
- d) Specimen Packaging: Use triple packaging layers (IATA) where the 3 layers are:
- Layer 1: The primary container should be watertight and preferably screw capped. Ensure the container containing VTM and swabs is tightly closed and wrapped with absorbent paper
 - Layer 2: The second layer should be a watertight sealed plastic bag (Ziploc bag)
 - Layer 3: Strong outer packaging and well labelled

Disinfect outer package with 0.5% sodium hypochlorite solution then place the package in a cooler box with ice packs.

Figure 2: Triple packaging for COVID-19 samples



The testing laboratory must be notified on anticipated COVID-19 specimens before sending the sample. This will ensure proper and fast processing of samples and to assure adequate biosafety measures are taken in the laboratory.

- e) Specimen Storage: If samples cannot be shipped immediately to the lab, they should be stored as per the guidelines below:
 - a. NP/OP specimen at 4 °C for ≤ 5 days and -70 °C > 5 days
 - b. Sputum at 4 °C for ≤ 48 hours and -70 °C > 48 hours
 - c. BAL at 4 °C for ≤ 48 hours and -70 °C > 48 hours

During storage, temperatures must be monitored daily.

- f) Specimen transportation– Follow the in-country guidelines and National biosafety and biosecurity guidelines for the safe transport of infectious substances and diagnostic specimens (see Appendix 4).

9.5 Laboratory Testing

Current laboratory diagnostics for COVID-19 in Kenya is based on nucleic acid amplification tests (NAAT) that detect viral RNA. In future, immunoassays will be adopted as and when they become available and approved.

All laboratories MUST get prior approval from MOH to conduct tests for COVID-19 following assessments using the WHO 2019 SARS-CoV-2 Laboratory Assessment Tool⁴. Only samples that meet MOH criteria for testing will be received at public health laboratories⁵. Samples should be carefully handled not only to prevent exposure to infection but also to retain the integrity of the sample to ensure accuracy of measure (See Appendix 5). Testing for the virus should only be done using WHO protocols (5) that have been approved for use in Kenya.

The appropriate quality assurance measures should be put in place to ensure the results released by the testing laboratories are accurate (see Appendix 8). All borderline positive results and inconclusive results should be repeated. Additionally, testing should also be repeated where the internal quality controls fail.

The turnaround time (TAT) from specimen collection to availability of results should be 24 hours or less to allow for both clinical management and outbreak response.

⁴ See reference 4

⁵ See Reference 5

All MOH approved COVID-19 testing laboratories will be required to submit the first 10 positives and 10 negative samples to NPHL for verification – See Appendix 9 This will be reviewed as per the workload and performance. Any inconclusive and repeatedly invalid results need to be verified by an institution designated by NPHL (see Appendix 7). If samples remain inconclusive after testing in the referral laboratory, another sample should be collected for repeat testing

9.6 Laboratory Biosafety Requirements

Risk assessment should be conducted to ascertain the state of preparedness of the laboratory to handle any Covid-19 samples using the WHO Lab assessment tool⁶ The assessment should assess the biosafety level of the lab, disinfection and waste management, safety conditions, use of safety equipment (PPE) and biosafety behavior, and staff health services

All staff performing testing should have received Biosafety training in the context of COVID-19⁷

9.7 Quality Assurance

The National Public Health Laboratories (NPHL) is the national coordinating laboratory mandated to oversee quality assurance of COVID-19 testing in the country. NPHLS will also liaise and consult with WHO appointed regional reference laboratories for quality assurance.

Quality assurance should be maintained at all phases of testing -pre-analytical (obtaining patient information, filling in requisition form, and taking the specimen sample), analytical (during testing) and post analytical (when interpreting the test results, reporting and results transmission). The reliability and reproducibility of the results should be measured through internal and external quality assurance processes, and corrective action taken when the established quality criteria has not been met. Corrective actions should be reviewed by laboratory management weekly to address the root causes that require financial or management input.

- i. **Positive and Negative kit controls** must be included during each test run to verify that the test is working properly, and the test run was valid and has produced acceptable results. Laboratories can add other internal controls to their assays to augment kit controls. Closed systems and rapid tests have in built QCs and these should be monitored and documented for each test. Testing should be repeated in the case of failed internal quality controls and corrective action done to determine the root cause of the failed run.
- ii. **External quality assessments** The National Public Health Laboratories (NPHL) is responsible for coordinating proficiency panel testing and ultimately monitoring the

⁶ See Reference 4

⁷ See reference 6

quality of testing for COVID 19 diagnostics nationally. NPHL will obtain EQA panels from WHO and other supporting partners and distribute them to enrolled laboratories.

- iii. **Confirmatory testing** - All MOH approved COVID-19 testing laboratories will be required to submit the first 10 positive and 10 negative samples to NPHL for verification.
- iv. **Calibration of Equipment:** Crucial equipment used in testing, and specifically manual and automated thermocycler platforms, pipettors, and biosafety cabinets must be calibrated and certified. Maintenance records should be available in the laboratories.

Additionally, SOPs should be adhered to and staff competency assessed.

9.8 Data management - Reporting of cases and test results

The specimen and data generated during testing shall remain the property of the MoH and all the facilities holding the samples and data will be doing this at the behest of the MoH and no sharing or transfer of the material will happen without the approval of the DG in consultation with PS. The central database will be at a location determined by the PS of the MoH

National reporting requirements should be strictly adhered to.

- i) The laboratory should have measures and a procedure to ensure information security.
- ii) There should be mechanisms for internal review of results before release as guided by an SOP for review and release of results. This is to ensure there are no errors such as transcription mistakes.
- iii) Following confirmation of results as per these guidelines, the testing laboratory should submit the results to the requesting clinicians to facilitate case management. The comments section of the report should include:
 - Test reactivity- positive/negative
 - Interpretation based on clinical situation of patient (contact, quarantine, Pneumonia, convalescent etc.,)
 - Recommended next steps such as repeat testing.
- iv) All test results, whether positive or negative, should be reported within 24 hours to the head of the NPHL using the Daily Covid-19 Laboratory Results Submission Template (Table 3) as per the Laboratory Testing Algorithm. Automated reporting systems will also use the same reporting mechanisms as and when they become available. If the results are inconclusive or there are failed runs, a repeat assay should be conducted within the next 24 hours-

- v) A technical team will verify the results and the head NPHL will report the results to the EOC and the Director General of Health, who will then report to the Cabinet Secretary of Health
- vi) The EOC will communicate the results to the facility and the Rapid response Teams at the county and sub-county levels
- vii) Following confirmation of results as per these guidelines, the testing laboratory should submit the results to the requesting clinicians to facilitate case management. The comments section of the report should include:
 - Test reactivity- positive/negative
 - Interpretation based on clinical situation of patient (contact, quarantine, Pneumonia, convalescent etc.,)
 - Recommended next steps such as repeat testing.
- viii) Laboratories should notify NPHL on a weekly basis, number of samples received, number tested and an anticipated testing backlog.

Table 3: Daily Covid-19 Laboratory Results Submission Template

This template should be fully filled with all the relevant information and submitted to the Head NPHL by 6.00 am every day. It should be accompanied by an updated line-list of all confirmed cases since the outbreak was first reported in the Country							
Date	Testing Laboratory	Cumulative number of samples tested as at last update	Number of samples tested since last update	Cumulative number of samples tested to date	Cumulative positive tests as at last update	Number of new Positive tests	Cumulative Positive samples since onset of outbreak
Total							

9.9 Sample Management

The sample management will be as per the procedures determined by NPHLS and KEMRI as the primary custodians of the samples on behalf of the MOH.

9.10 Specimen archival

The COVID-19 specimens are a national resource for use in research investigations towards a better understanding of the pandemic and for development of diagnostic tools. Every effort should be made to archive COVID-19 specimen. At least a 1 ml COVID-19 specimen should be sent to the MOH biorepository for archiving in accordance to guidance from the MOH. The procedure for archiving shall include proper documentation on the samples for archival,

timeliness for archival, indexing, procedure for retrieval in cases of retesting, access to the archive, maintenance and monitoring of proper storage conditions. (See Appendix 6). No research work or testing outside COVID-19 will be done on these samples without approval of the MOH and a mandated institutional ethical review boards (IRB).

10 Scale up Plans

Full scale targeted testing/surveillance will rely on scale-up of molecular (polymerase chain reaction [PCR]) testing capacity to support a minimum of 6000 samples daily. Reagent and other supply availability (e.g., RNA extraction kits, nasopharyngeal swabs, etc.) may be limiting factors and will need to be continuously monitored when rolling out targeted testing, to ensure adequate resources are retained for testing priority samples across the country.

The government needs to utilize this opportunity to develop its manual PCR systems which will also form a basis for setting up systems for surveillance platforms that will inform future rapid response for diseases.

There is need to establish and strengthen regional laboratory capacity based on the six (6) regional economic blocks.

1. **North Eastern Counties** comprising of seven (7) counties namely; Garissa, Wajir, Mandera, Isiolo, Marsabit, Tana River and Lamu.
2. **North Rift Counties** comprising of seven (8) counties namely Uasin Gishu, Trans-Nzoia, Nandi, Elgeyo Marakwet, West Pokot, Baringo, Samburu and Turkana.
3. **Lake Region counties** comprising of thirteen (14) counties namely Migori, Nyamira, Siaya, Vihiga, Bomet, Bungoma, Busia, Homabay, Kakamega, Kisii, Kisumu, Nandi, Trans Nzoia and Kericho.
4. **Counties in the Coast Region** comprising of six (6) counties namely, Tana River, Taita Taveta, Lamu, Kilifi, Kwale and Mombasa
5. **South Eastern Counties** comprising of three (3) counties namely Kitui, Machakos and Makueni.
6. **Mt. Kenya counties** Comprising of ten (10) counties namely Nyeri, Nyandarua, Meru, Tharaka Nithi, Embu, Kirinyaga, Murang'a, Laikipia, Nakuru and Kiambu.

Planning should continue to incorporate additional molecular testing platforms and capacity that are projected to become available (e.g., Cepheid GeneXpert).

Planning should also continue for utilization of future validated serologic testing platforms for determination of prevalence, potential immunity, and special surveillance use cases (e.g., dead body surveillance).

11 Appendices

11.1 Appendix I – MOH COVID-19 Case Definition (as of 10th June, 2020)

Case and contact definitions are based on the current available information and are regularly revised as new information accumulates. updates to definitions which may affect the interpretation of surveillance data.

Suspect case

A. A patient with acute respiratory illness (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath), AND a history of travel to or residence in a location reporting community transmission of COVID-19 disease during the 14 days prior to symptom onset;

OR

B. A patient with any acute respiratory illness AND having been in contact with a confirmed or probable COVID-19 case (see definition of contact) in the last 14 days prior to symptom onset;

OR

C. A patient with severe acute respiratory illness (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath; AND requiring hospitalization) AND in the absence of an alternative diagnosis that fully explains the clinical presentation.

Probable case

A. A suspect case for whom testing for the COVID-19 virus is inconclusive.¹ OR

B. A suspect case for whom testing could not be performed for any reason.

Confirmed case

A person with laboratory confirmation of COVID-19 infection, irrespective of clinical signs and symptoms.

See laboratory guidance for details:

Contact

A contact is a person who experienced any one of the following exposures during the 2 days before and the 14 days after the onset of symptoms of a probable or confirmed case:

1. Face-to-face contact with a probable or confirmed case within 1 meter and for more than 15 minutes;
2. Direct physical contact with a probable or confirmed case;
3. Direct care for a patient with probable or confirmed COVID-19 disease without using proper personal protective equipment; OR
4. Other situations as indicated by local risk assessments.

Note: for confirmed asymptomatic cases, the period of contact is measured as the 2 days before through the 14 days after the *date on which the sample was taken* which led to confirmation.

11.2 Appendix 2 - case investigation form



V08052020

MINISTRY OF HEALTH
Division of Disease Surveillance and Surveillance
Case investigation form for 2019 Novel Coronavirus (COVID-19)

Date of reporting to national level:

D[][]/M[][]/Y[][][][]

Why was the person tested for COVID-19 or investigation being conducted?

- ☐ Contact with confirmed case
☐ Presented at health facility ☐ Surveillance
☐ Point of entry detection
☐ Repatriation ☐ Other

Date of investigation: D[][]/M[][]/Y[][][][]

Section 1: Patient information

1.1 National Id No. for Kenyans:/Passport No _____

1.2 Full name (3 names): _____

1.3 Mobile phone No _____ 1.4 Email address _____

1.5 Race: ☐ African ☐ Asian ☐ European/American ☐ Other _____

1.6 Citizenship: ☐ Kenyan ☐ others (specify) _____

1.7 Age: [][] in years

1.8 Sex : ☐ Male ☐ Female

1.9 Marital status ☐ Married ☐ Single ☐ Divorced

1.10 Level of education ☐ No formal education ☐ Primary ☐
Secondary ☐ Tertiary

1.11 Is the case alive ☐ Yes ☐ No

1.12 Place where the case was investigated: ☐ Household ☐
Mass Testing

☐ Quarantine ☐ Health Facility Specify health facility

1.13 Patient usual place of residence County: _____ Sub county:
Ward: _____ (village/estate): _____

1.14 Next of Kin Name _____ Mobile Number _____

Section 2: Clinical information

Patient clinical course

2.1 Date of onset of symptoms: D[][]/M[][]/Y[][][][]

☐ Asymptomatic ☐ Unknown

2.2 Admission to hospital: ☐ No ☐ Yes ☐ Unknown

2.2.1 If yes, first date of admission to hospital:

D[][]/M[][]/Y[][][][]

2.2.2 Name of hospital:

2.2.3 Patient taken to isolation ☐ No ☐ Yes ☐ Unknown

If yes, date of isolation: D []

[]/M[][]/Y[][][][]

2.2.4 Patient admitted to ICU ☐ No ☐ Yes ☐ Unknown

2.2.5 Was the patient ventilated: ☐ No ☐ Yes ☐ Unknown

2.3 Health status at time of reporting:

☐ Stable ☐ Severely ill ☐ Dead
☐ Unknown

2.3.1 Outcome ☐ Still in hospital ☐ Discharged ☐ Death

2.3.2 Date of outcome (discharged, death) if applicable:

D [][]/M [][]/Y [][][][]

2.4 Patient symptoms (check all reported symptoms):

<input type="checkbox"/> History of fever / chills	<input type="checkbox"/> Shortness of breath	<input type="checkbox"/> Pain (check all that apply)
<input type="checkbox"/> General weakness	<input type="checkbox"/> Diarrhoea	() Muscular ()

Chest

☐ Cough

☐ Nausea/vomiting

() Abdominal ()

Joint

☐ Sore throat

☐ Headache

☐ Runny nose

☐ Irritability/Confusion

☐ Other, specify _____

Have the symptoms resolved? Yes ☐ No ☐ Unknown ☐

If Yes, Date of symptom resolution _____

Unknown ☐

Patient signs:

2.5

Temperat

ure ____ °C

2.6

Check all

observed

signs:

☐ Pharyngeal exudate

☐ Coma

☐ Abnormal lung

X-Ray findings

☐ Conjunctival injection

☐ Dyspnea / tachypnea

☐ Seizure

☐ Abnormal lung auscultation

☐ Other, specify: _____

2.7 Underlying conditions and comorbidity (check all that apply):

☐ Pregnancy (trimester: _____)

☐ Post-partum (< 6 weeks)

☐ Cardiovascular disease, including hypertension

☐ Immunodeficiency, including HIV

☐ Diabetes

☐ Renal disease

☐ Liver disease

☐ Chronic lung disease

☐ Chronic neurological or neuromuscular disease

☐ Malignancy

☐ Smoking (current or former smoker)

☐ Other, specify: _____

Section 3: Exposure and travel information in the 14 days prior to symptom onset (prior to reporting if asymptomatic)

3.1 Occupation: (tick any that apply)

☐ Student

☐ Health care worker

☐ Other, specify: _____

- ☐ Working with animals ☐ Health laboratory worker

3.2 Has the patient **travelled** in the 14 days prior to symptom onset? ☐ No ☐ Yes ☐ Unknown

If yes, please specify the places the patient travelled:

	Country	City	Date
1	_____	_____	_____
2	_____	_____	_____
3	_____	_____	_____
4	_____	_____	_____

3.3 Has the patient **visited any health care facility(s)** in the 14 days prior to symptom onset?

- ☐ No ☐ Yes ☐ Unknown

3.4 Has the patient had **close contact**¹ with a person with acute respiratory infection in the 14 days prior to symptom onset?

- ☐ No ☐ Yes ☐ Unknown

If yes, contact setting (check all that apply):

- ☐ Health care setting ☐ Family setting ☐ Workplace ☐ Unknown

☐ Other, specify: _____

3.5 Has the patient **had contact with a probable or confirmed case** in the 14 days prior to symptom onset?

- ☐ No ☐ Yes ☐ Unknown

If yes, please list unique case identifiers of all probable or confirmed cases:

Case 1 identifier. _____ Case 2 identifier. _____ Case 3 identifier. _____

If yes, contact setting (check all that apply):

- ☐ Health care setting ☐ Family setting ☐ Workplace ☐ Unknown ☐ Other, specify: _____

If yes, location/city/country for exposure: _____

Section 4: Laboratory Information

Specimen collection (To be completed by the health facility)

4.1 Was specimen collected? ☐ 1=Yes 2=No

If no, why?

.....

4.2 Date(s) of specimen collection: D[][]/M[][]/Y[][][][]
4.3 Specimen type: ☐ NP Swab ☐ OP Swab ☐ Serum ☐ Sputum ☐
Tracheal Aspirate
Other (specify): _____

4.4 Date specimen send to the lab: D[][]/M[][]/Y[][][][]

(To be completed by the confirming lab)

Date specimen received in the lab:
D[][]/M[][]/Y[][][][] Time[][]:[][]

4.5 Name of confirming lab: _____

4.6 Please specify which assay was used: _____

4.7 Preliminary lab results: _____

4.8 Has sequencing been done? ☐ Yes ☐ No ☐ Unknown

4.9 Date of laboratory confirmation: D[][]/M[][]/Y[][][][]

4.10 Name of the Interviewer/investigator: _____
Sign _____

¹ Close contact' is defined as: 1. Health care associated exposure, including providing direct care for nCoV patients, working with health care workers infected with novel coronavirus, visiting patients or staying in the same close environment of a nCoV patient. 2. Working together in close proximity or sharing the same classroom environment with a with nCoV patient. 3. Traveling together with nCoV patient in any kind of conveyance. 4. Living in the same household as a nCoV patient.

11.3 Appendix 3 -Sample Collection SOP for Specimen Collection For COVID-19 Confirmation

Description

The purpose of this SOP is to provide guidance on to healthcare providers and public health staff on specimen collection to detect the etiologic agent during COVID-19 disease outbreak. Rapid collection and testing of appropriate specimens from suspected cases is a priority and should be guided by a laboratory expert or a trained clinical staff.

Samples are collected from persons:

3. Persons meeting the case definition for COVID -19 infection. This is defined as Any person with any acute respiratory illness (fever or cough or difficulty in breathing) AND at least one of the following:
 - A history of travel to or residence a country confirmed cases in the 14 days prior to symptom onset, or
 - Close contact* with a confirmed or probable case of COVID-2019 in the 14 days prior to illness onset, or
 - Close contact* with an individual with a history of respiratory illness and travel to a country with confirmed cases within the last 30 days, or
 - Worked or attended a health care facility in the 14 days prior to onset of symptoms where patients with hospital-associated COVID-2019 infections have been reported.
4. Persons in quarantine as per the MoH definitions having travelled from a country with confirmed cases within the last 30 days

Safety Considerations

All clinical specimens from patients are potentially infectious. Thus, the following safety precautions must be followed.

1. All personnel should be aware of the potential health hazards involved and always adopt standard precautions.
2. The PPE recommended for this procedure include N-95 masks, gloves, protective eye wear (goggles or face shield), closed shoes, and coverall/ N-gown.
3. During packaging and shipment of specimens from suspected cases, ensure that all items required for triple packaging are readily available.

In case of accidental exposure to infected materials from the patient, report immediately to your supervisor and based on the protocol in the facility.

Equipment and Materials

Assemble all equipment for specimen collection

- i. Cryovial pre-filled with 4.5 ml virus transport media (VTM) tubes stored at 4°C. If unavailable, 3 ml VTM tubes may be used. e
- ii. Individually wrapped swabs with flexible plastic shafts (drayon, rayon, or polyester-fiber swabs). **Do not** use wooden swabs.
DO NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit some molecular assays.
- iii. Plastic leak-proof primary container
- iv. Waterproof marker
- v. Leak-proof specimen transportation bags (zip lock bags) and secondary container.
- vi. Cool box and ice packs
- vii. Absorbent materials-Paper towel
- viii. Case Investigation Form and Lab Request Forms. (Appendix 4.2)
- ix. Plastic document sleeve
- x. masking tapes

PPE and waste management supplies as required based on standard precautions:

- xi. Coverall
- xii. Disposable Gloves
- xiii. N-95mask
- xiv. Eye protection e.g. goggles or face shield
- xv. Wooden tongue depressors
- xvi. 0.05% bleach hand spray/ alcohol-based hand rub for hand hygiene
- xvii. 0.5% bleach
- xviii. Leak-proof infectious waste bags: one for disposable material (destruction) and infectious waste and one for reusable materials (disinfection)

Preliminaries Preparations

- i. Plan the sample collection
- ii. Wash and sanitize your hands.
- iii. Put on the appropriate PPEs
- iv. Remove VTM tubes from the cooler box/refrigerator.
- v. Prepare the client for sample collection
- vi. Fill out the lab section in the COVID 19 questionnaire and the LRF
- vii. Label the prefilled VTM cryovial and return it into the cryobox
- viii. Disinfect the pair of scissors using the 70% alcohol pads. NOTE the cutting edges and tip of the scissors should be in the air and not touching any surface.
- ix. Reassure the patient and instruct them on safety measures. Be sure to advice the patient of potential discomfort during sample collection. Also explain that the procedure will take a few minutes

Collection of nasopharyngeal (NP) swabs

1. Have the patient sit on a chair against a wall. Place the head against the wall and angle their head upwards to visualize the nasal area clearly. Adequate lighting is necessary.
2. Ensure you stand on the patient's side as s/he is likely to sneeze to avoid the risk of contamination.
3. The patient should not blow their noses, just clean the outside of the nose. (Blowing the nose may lead to less optimal samples)
4. In case of a child, instruct the parent/guardian to hold the child on his/her lap in such a way that the child cannot grab the swab or hyperextend the neck. The guardian should hold the child's head securely and tip the head backwards slightly. Head and arms should be immobilized.
5. Measure the distance from the nose to the ear to get an estimate of the distance the swab should be inserted.
6. Remove cap from one prefilled cryovial with VTM media and place the cap in the lid of cryobox.
7. Remove the swab stick from the packaging holding it and peel off as indicated on the packaging.
8. Ensure that your swab is not damaged or expired. Sterility should be maintained
9. Insert the swab through one nostril straight back (not upwards), along the floor of the nasal passage until reaching the posterior wall of the nasopharynx.
10. Rotate swab gently and leave in place for up to 5 seconds to absorb secretions
11. Remove the swab slowly and insert swab to the bottom of the VTM in cryovial
12. Raise the swab slightly and cut the shaft of the swab from the neck with disinfected scissors. Allow the bottom position of the swab (i.e. the tip) to drop into the tube. Discard the remaining shaft into biohazard waste bag.
13. Tighten the screw cap top of the cryovial securely.
14. Label each specimen container with the patient's name, specimen type, and the date collected
15. Disinfect scissors using 70% alcohol swab

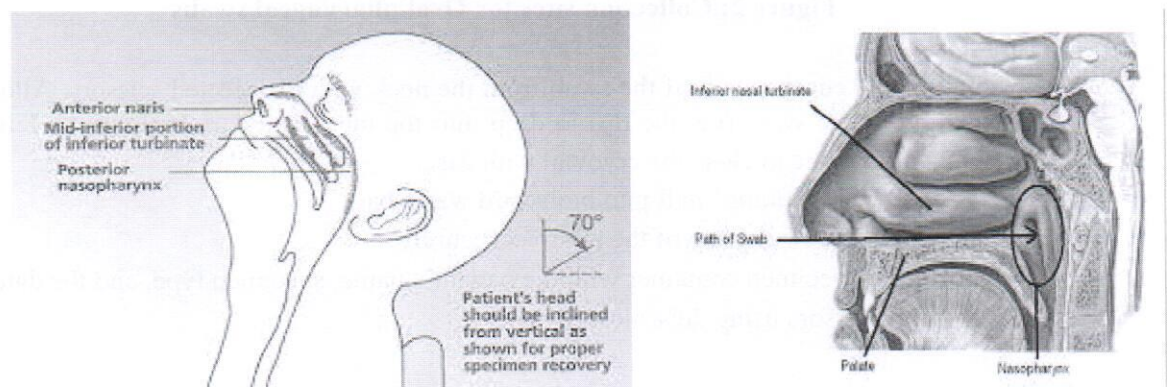


Figure 1: Collection sites for Nasopharyngeal swabs

Collecting the oral pharyngeal (OP) swab.

1. Have the patient sit on a chair in a comfortable position with adequate lighting.
2. In case of a child, instruct the parent/guardian to hold the child on his/her lap in such a way that the child cannot grab the swab. The guardian should hold the child's head securely and immobilize the child's hands.
3. Inform the patient that the smear may be uncomfortable for a short time and may trigger a gag reflex.
4. Ensure you stand at a safe distance to avoid the risk of contamination during specimen collection.
5. Ask the patient to open their mouths wide, protrude their tongue forward and say "ah"
6. Depress the patients tongue using a tongue depressor.
7. Gently insert swab into the posterior pharynx and tonsillar areas.
8. Rub swab over both tonsillar pillars and posterior oropharynx and **avoid** touching the tongue, teeth, and gums.
9. Place swab directly into the cryovial containing the NP swab from the same patient ensuring that the tipped side gets into the VTM.

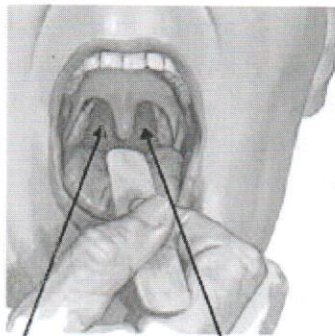


Figure 2: Collection sites for Oral pharyngeal swabs

10. Raise the swab slightly and cut the shaft of the swab from the neck with disinfected scissors. Allow the bottom position of the swab (i.e. the tip) to drop into the tube. The part of the swab left in the VTM should allow one to close the cryovial with ease.
11. Discard the remaining shaft into biohazard waste bag.
12. Tighten the screw cap top of the cryovial securely.
13. Label each specimen container with the patient's name, specimen type, and the date collected
14. Disinfect scissors using 70% alcohol swab

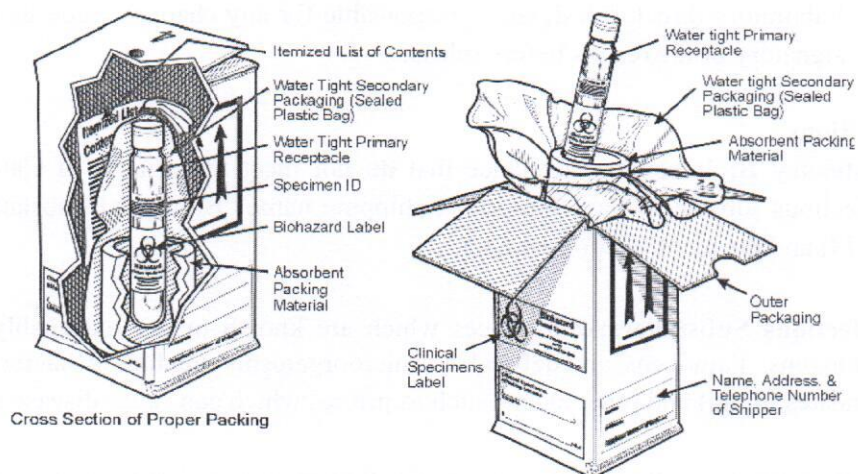
Note: If specimens will be examined within 48 hours after collection, keep specimen at 4°C and ship on wet ice or refrigerant gel-packs, otherwise store frozen at $\leq -70^{\circ}\text{C}$ and ship on dry ice. Avoid the repeated freezing and thawing of specimens. Viability pathogens from specimens that are frozen and then thawed is greatly diminished and may result in false-negative test results.

Collection of Sputum

1. Educate the patient about the difference between sputum and oral secretions.
2. Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile screw-cap collection cup or sterile dry container.
3. Label the vial or container with the patient's name, ID number, specimen type, and date collected. Specimens are to be examined within 48 hours after collection therefore keep specimen at 4°C and ship on wet ice or refrigerant gel-packs, otherwise store frozen at $\leq -70^{\circ}\text{C}$ and ship on dry ice.

Transportation

1. Pack the specimen using a triple packaging system (see below).
 - Layer 1: The primary container should be watertight. Ensure the container containing VTM and swabs is tightly closed and wrapped with absorbent paper
 - Layer 2: The second layer should be a watertight sealed plastic bag (Ziploc bag)
 - Layer 3: Strong outer packaging such as a cool box or Styrofoam containing ice packs. Ensure it is labeled with a hazard sticker and/or UN marking 3373 for category B material.
2. Place the Case Investigation form and the LRF in a plastic sleeve in the cool box.
3. Label the package with the address of the contact person's name for the laboratory you are sending the specimen, Address and phone contacts. Also indicate where the specimen is referred from and the contact person and their phone contacts.



4. Decontaminate the tertiary container using 0.5% bleach (in our case Jik)
- Remove the PPE following the guidance on donning and doffing and ensure you observe the standard precautions. Ensure that the package is transported to the reference laboratory within 24 hours

11.4 Appendix 4 - SOP for Transportation of COVID 19 samples

1. Purpose/Applicability:

- a. **Introduction:** The understanding of the transmission of the disease caused by COVID 19 virus is limited. Therefore, handling of samples from cases and suspected cases should always be by personnel with demonstrated capability to strictly observe relevant protocols.
- b. This Standard Operating Procedure (SOP) is to ensure that all laboratory personnel understand the procedures of packaging and transportation of infectious material, cognizant of the “safety” of specimen and the laboratory workers.
- c. To give guidelines applicable to the transportation of infectious substances and diagnostic specimens both nationally and internationally.
- d. Provide information for identifying and classifying the material to be transported and for its safe packaging and transport.
- e. Give guidelines on safe packaging and shipment of dry ice.

2. Responsibilities:

- a. Laboratory Supervisor/designee and all laboratory staff must make sure that the SOP is implemented and utilized as written.
- b. Laboratory staff and Laboratory supervisor/designee are responsible for shipping samples as indicated in the SOP.
- c. Laboratory director/designee is responsible for any changes made in this SOP and the final signatory of the results before release.

3. Definitions

- a. **Category B:** Infectious substance that do not meet the criteria of Category A. Category B infectious substances have the proper shipping name “Biological Substance, Category B” (UN 3373) and the identification number.
- b. **Infectious Substances:** Substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsia, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.
- c. **Packaging:** (Non-Radioactive Material). Receptacles and any other components or materials necessary for the receptacle to perform its containment function and to ensure compliance with the minimum packing requirements of these Regulations.
- d. **Packing:** The art and operation by which articles or substances are enveloped in wrappings and/or enclosed in packaging or otherwise secured.

4. Warnings and Precautions:

- i. Risk assessment should be performed for individual laboratories that ship and receive samples
- ii. Standard and pathogen specific precautions should always be observed when handling COVID 19 suspect samples.
- iii. All body fluids and their products should be considered as infectious.
- iv. Appropriate Personal Protective Equipment will always be used when handling all COVID 19.
- v. Make sure that the information on the tubes and vials matches the data on the laboratory request, laboratory referral and biological material tracking form as applicable.
- vi. Staff transporting and receiving samples MUST be trained and should have spill management kits.

5. Materials

- a. Cool boxes (Outer Rigid Container)
- b. Ice packs
- c. Adsorbent material
- d. Spill Kits
- e. Primary Container (VTM vial)
- f. Secondary containers.
- g. A waterproof bag for sample-packaging list.
- h. Appropriate PPE

6. Procedures

1. Packaging and transporting of suspected COVID 19 samples from one hospital to the testing, referral and/or archiving facility.
- i. COVID 19 is Category B infectious substances must be triple packaged and transported in ice packs and temperature should be within 2-8°C and if possible, temperature monitored. Ensure if using ice packs to pad them well so that they do not freeze the sample enroot.

NOTE: Respiratory specimens must be kept cool: -

- Samples on transit to the testing laboratory must be transported at 4 °C
 - Storage till testing should be:
 - ≤5 days: 4 °C)
 - >5 days: -70 °C)
 - If transported >72 h, keep at -70°C (ship on dry ice or Liquid Nitrogen)
 - Avoid repeated freeze/thaw cycles (do not use frost-free freezers)
- ii. All samples should be accompanied by the COVID 19 Lab Requisition Form that contains the all details of the patient for those samples delivered to the testing laboratories and for verification of sample received in the laboratory.
 - iii. The samples sent through use of courier should have the following details.

1. Sender's name and address
 2. Recipient's name and address
 3. Responsible person contacts telephone number.
- iv. For all the samples that are sent to the National Public Health Laboratories for permanent archiving the following details should be captured in the sample transfer form and upon reception a copy is sent back to the facility for acknowledgment of receipt of specimens.
1. Sample ID
 2. Facility
 3. Sample type
 4. Date moved
 5. Moved to
 6. Box Number
 7. Position number.
- v. **Documentation of transported samples**
1. All samples shipped out of the facility should be approved by the laboratory manager and documentation of the same.
 2. All samples shipped to the National Public Health Laboratories should use the sample transfer form for permanent archiving.
- vi. **Packing for Samples for Shipment**
1. Absorbent material packed between the primary and secondary containers enough to contain any spill that may occur from the primary container.
 2. The shipment will be packed with sufficient coolant material to ensure the required temperatures are maintained throughout the transport. Coolant packs stored in the freezer should be used. However, samples should not be placed directly on frozen packs.
 3. Dry ice will be used for transporting frozen specimen.

Sample Transfer Form

Sample ID	Facility	Date Shipped	Date Received	Moved to	Box Number	Position

Purpose of transfer

.....

Transferred by: Sign.....

Date.

Authorized by: Sign

Date

Received by: Sign

Date

11.5 Appendix 5 - SOP for Pre-Analytical Handling Of Covid-19 Suspect Samples

1. Purpose

To establish a standard procedure for receiving COVID-19 suspect samples in the testing laboratory.

2. Summary (Background)

The SOP provides an overall guideline of the pre-analytical stages for laboratories handling the COVID-19 outbreak samples in Kenya. The pre-analytic testing phase includes specimen transportation to the designated laboratory, reception and verification of samples in the laboratory. The samples should be carefully handled during reception not only to prevent laboratory personnel from exposure to infection but also to retain the integrity of the sample to ensure accuracy of measurand. Pre-analytical phase of laboratory sample management must have rigorous control measures to avoid error that could lead to wrong laboratory reporting.

3. Applicability

All Laboratory staff handling the COVID-19 suspect samples in the laboratory.

4. Safety

This section specifies actions and considerations to be considered such as known hazards specific to this SOP and biosafety practices required for the safe execution of its procedures.

- A. Each laboratory should have a Biosafety manual/protocol available which describes the essential biosafety, chemical, fire and electrical safety requirements to protect staff, the community and the environment. All staff should be familiar with the contents of this manual/protocol and should proceed accordingly.
- B. Practices, safety equipment and PPE that apply to Biosafety Level III laboratories must be followed.
- C. All laboratory staff should be trained on Biosafety level III protocols and made aware of the risks involved when working with highly contagious specimen.
 - I. COVID-19 samples should be handled only by laboratory professionals fully trained and qualified to handle high-risk infectious specimen.
 - II. The number of people involved with the management of the sample should be maintained at a minimum. All non-essential staff should evacuate the area where the sample is to be processed
 - III. New staff or trainees are not allowed in the laboratory when samples are being processed.

Note: Contact with the samples should always be restricted and unnecessary manipulation should be avoided.

- D. All laboratory personnel should be aware of the potential health hazards involved and be trained to adopt standard precautions.
- E. Laboratory staff should don full PPE including N95 face masks, face shields/goggles, gloves, disposable waterproof shoe covers, laboratory cap and full suit disposable Tyvek

or disposable lab coat before handling the package containing samples delivered to the laboratory. **Note:** Staff should wear two pairs of gloves (double glove) when handling samples

- F. All biohazardous liquid, solid waste and sharps are handled as per the waste handling policies⁸
- G. Upon leaving the laboratory, process of doffing PPE must be strictly adhered to and the PPE placed in a biohazard bag

Note: Samples collected from human sources are potentially contaminated with human viruses such as Hepatitis B and HIV, hence, caution should be exercised when handling all materials associated with protocol and laboratory staff should be appropriately vaccinated.

5. Pre-analytical procedures:

- A. Wear appropriate full Personal protective equipment as described above in sub-clause 4.5
- B. Place the cool box on the laboratory bench and disinfect using 0.5% hypochlorite solution (bleach).
- C. Ensure there is at least 10 minutes contact time for the bleach to actively destroy any contaminant on the cool box. **DO NOT OPEN THE COOL BOX.**
- D. Place the cool box in a functional Biosafety cabinet level II and open the cool box. Remove contents and disinfect the inside of the cool box using 0.5% hypochlorite solution (bleach)⁹.
- E. Disinfect the triple packaging container, the package/zip lock bag containing the lab requisition forms and the ice packs removed from the cool box using 0.5% hypochlorite solution (bleach). Allow contact time of 10 minutes before wiping off the bleach.
- F. Place the ice packs back in the disinfected cool box or in the freezer component of a refrigerator.
- G. Remove the primary receptacle containing the samples from the secondary leak proof container and disinfect the exterior. **Note:** Observe for any leakage of samples
- H. Remove samples from the primary receptacle and arrange them on a cold block to retain cold chain.
- I. Verify the samples against the lab requisition forms.
- J. Place laboratory barcodes or laboratory IDs on the sample vials and on the corresponding requisition forms
- K. Heat inactivate samples at 60°C for 60 minutes
 - a. For molecular diagnosis of any pathogen, the inactivation processes should ensure a total loss of infectiousness while conserving the integrity of nucleic material
 - b. According to an article published by the World Health Organization in 2014, samples for PCR amplification can be inactivated through heat treatment at 60°C for a 60-minute duration¹⁰.
 - c. To increase biosafety, use of denaturing solutions (lysis buffers used in extraction stages of sample processing) in combination with heat inactivation is recommended as per the testing protocol used.
 - d. As the samples are incubating, prepare a sample log sheet using the laboratory requisition forms. This is to aid in:

⁸ See Reference 6

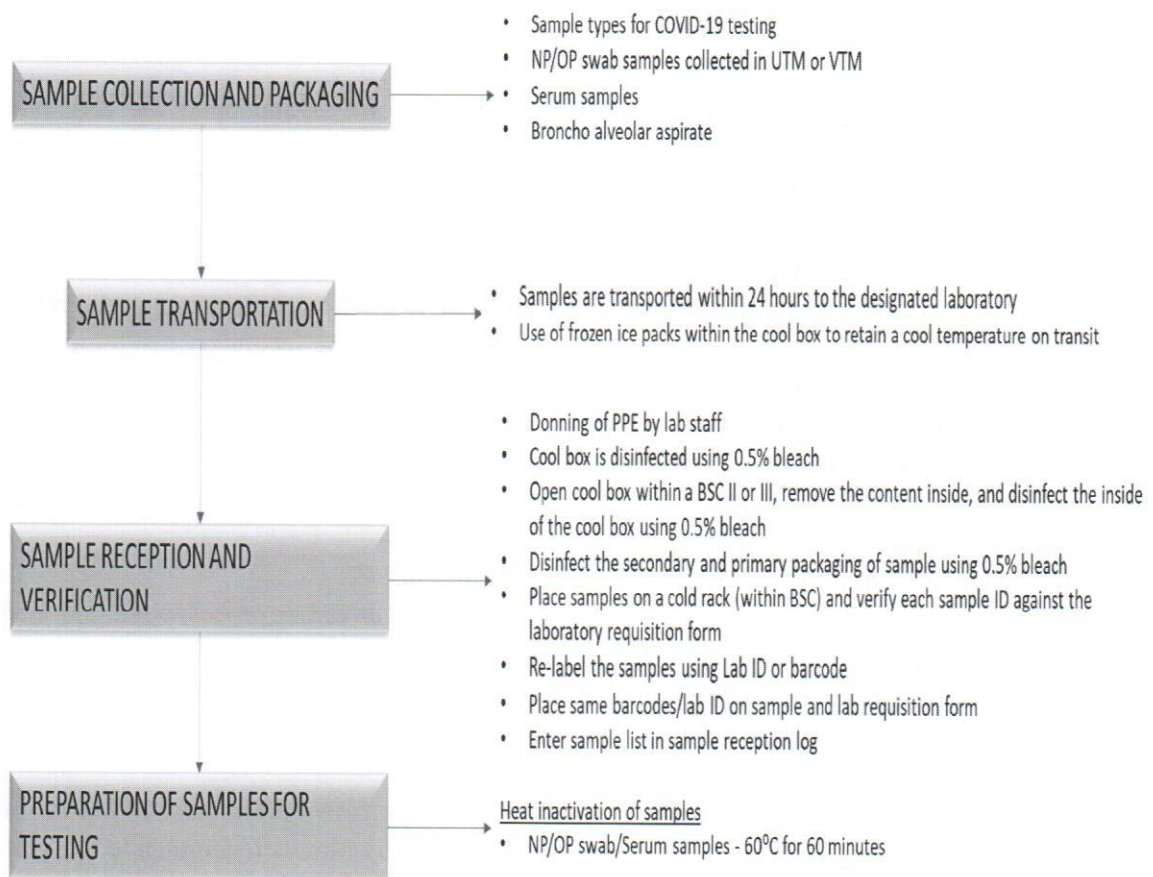
⁹ See Reference 6

¹⁰ See Reference 7

- i. Listing the order in which samples are to be tested to accurately test and report each sample.
- ii. Creating a sample reception log to note the reception date, the sample type, laboratory staff receiving the samples and sample rejection as per criteria established by the laboratory.
- iii. Other comments such as observed sample leakage or inappropriate sample transportation temperature. Should be noted in the sample reception log
- iv. Process the sample swabs as per the laboratory's COVID-19 testing SOP

Figure 3 - Job aid – pre analytical workflow

PRE-ANALYTICAL LABORATORY WORK FLOW



11.6 Appendix 6 - SOP for Sample Archiving of COVID-19 Suspect Samples

1. Purpose/Applicability

This SOP will describe the handling and archiving of COVID 19 samples.

This SOP applies to all laboratory personnel that will be archiving of COVID-19 samples.

2. Scope/ Responsibilities

- i) Laboratory Supervisor and all laboratory staff must make sure that the SOP is implemented and utilized as written.
- ii) Laboratory Technologist/ Technician and Laboratory supervisor are responsible for reviewing, signing and dating all validated reports.
- iii) Laboratory director or designee is responsible for any changes made in this SOP.

3. Terms and abbreviations

- i) SOP – Standard operating procedures
- ii) QC – Quality control
- iii) °C – degrees Centigrade
- iv) PIN – Patient Identification Number
- v) NA– Not Applicable

4. Equipment's, Reagents and materials: NA

5. Procedure

Processing

- i) Samples are processed according to specific testing SOPs per the laboratory procedures.
 - a. Remnant sample following testing should be aliquoted into 1 ml cryovials for storage. These samples should be uniquely identified and labeled as PIN-1, PIN-2, PIN-3, etc. according to the number of aliquots for tracking purposes.
 - b. Every effort should be made to ensure that there is at least one vial of remnant sample for archiving for samples that test positive for SARS-COV-2

Specimen archiving

1. COVID 19 samples will be stored at 4⁰C till the results have been verified and dispatched.
2. After results have been dispatched, samples will then be returned to the archiving section at 4⁰C accompanied by the sample list
3. These samples will be stored using the sample storage map indicating which sample is contained in what position of the box (Appendix 1)
4. Samples will be stored sequentially according to reception and/or PIN numbers for ease of identification and retrieval.

5. Individual laboratory may design their archiving depending on the type of freezers and storage boxes available. See Appendix 1 for a sample
6. Place the cryo-vial in the box position physically and indicate the sample number on the storage map.
7. Record the same number on the storage table - see Appendix 2
8. The person storing should indicate the time, date and initials.
9. Samples will be stored at -80°C

Specimen storage

1. Monitor the performance of the equipment used for specimen storage (refrigerator, freezer) and maintain a monitoring record (e.g. a daily temperature chart)
2. Have alternative storage capabilities (back-up) available in case of emergency, e.g. power failure or equipment failure

Specimen Use

1. At least a 1 ml COVID-19 specimen should be sent to the MOH biorepository for archiving in accordance to guidance from the MOH.
2. Use of COVID 19 specimens other than testing should be approved by Ministry of Health.
3. Approvals for use the samples MUST be availed to the Facility/Laboratory before any samples are issued for any other purpose other than testing and or for QA/QC purposes.
4. A record should be kept for the samples released for research and QA activities
5. Sample must never be discarded without approvals from the laboratory manager. After discarding any specimen update the information in the electronic/hard copy specimen tracking log (i.e. discard date and discarded by)

11.7 Appendix 6.1 Example of a Sample Storage Map

SAMPLES STORAGE RECORDS-_____

Freezer Identification _____

Rack Number. _____

Storage Box Number _____

Storage Temperature _____

A1	A2	A3	A4	A5	A6	A7	A8	A9
B1	B2	B3	B4	B5	B6	B7	B8	B9
C1	C2	C3	C4	C5	C6	C7	C8	C9
D1	D2	D3	D4	D5	D6	D7	D8	D9
E1	E2	E3	E4	E5	E6	E7	E8	E9
F1	F2	F3	F4	F5	F6	F7	F8	F9
G1	G2	G3	G4	G5	G6	G7	G8	G9
H1	H2	H3	H4	H5	H6	H7	H8	H9
I1	I2	I3	I4	I5	I6	I7	I8	I9

Name _____

Signature _____

Date _____

11.8 Appendix 6.2 Example of a Sample Table

Box Pos	Patient Identification # PIN	Lab #	Date Stored	Initial	QA Initial	Date Moved	Initial	QA Initial
A1								
A2								
A3								
A4								
A5								
A6								
A7								
A8								
A9								
B1								
B2								
B3								
B4								
B5								
B6								
B7								
B8								
B9								
C1								
C2								
..								
..								
..								
I9								

Legend: Pos= Position

12 Appendix 7 - SOP for Result Reporting and Dispatch

1. Purpose/Applicability:

- i. This document defines the general guidelines for result reporting and designates the appropriate supervisory personnel and individual laboratory personnel who are ultimately responsible for the review and release of results.
- ii. This SOP applies to all laboratories approved by the Ministry of health to carry out COVID-19 testing.

2. Responsibilities:

- i. Laboratory Supervisor/designee and all laboratory staff must make sure that the SOP is implemented and utilized as written.
- ii. Laboratory testing staff and Laboratory supervisor/designee are responsible for reviewing, signing and dating all verified reports.
- iii. Laboratory director/designee is responsible for any changes made in this SOP and the final signatory of the results before release.

3. Definitions

1. Requester – Institution/clinician that sends samples to the laboratory for COVID-19 testing.
 - a. COVID-19 – Coronavirus Disease 2019
 - b. NPHL- National Public Health laboratory
 - c. GCLP-Good Clinical Laboratory Practice
2. Materials
 - a. COVID – 19 Laboratory Requisition Form
 - b. Daily COVID-19 Laboratory Results Submission Template

Procedures - Guidelines for all results:

1. Clinical data is confidential, and it is imperative that only those designated by the lab director or his designees are involved in interpreting data for distribution to the requesting facility.
2. Only the Lab director or their designees can release patient information to the requester thus assuring participant confidentiality in accordance with GCLP guidelines
3. The laboratory staff running assays are responsible for reviewing the test results and QC data before reporting the results.
4. The section heads and/or designee are responsible for reviewing the results before taking them to the laboratory director/designee for review
5. The results are logged into the Daily COVID-19 Laboratory Results Submission Template. The following sections should be filled:
 - a. Number of Cases Tested Since Last Update
 - b. Cumulative number of tests done
6. The Lab director or his designate has the final check on all laboratory results and any query concerning the laboratory results should be directed to him/her.

7. Laboratory director/designee releases the duly completed Daily COVID-19 Laboratory Results Submission Template for tests done in the preceding 24 hours to the Head of National Public Health Laboratories. The report should be shared by 6am daily.
8. NPHL consolidates and analyses all COVID-19 results from designated testing laboratories,
9. NPHL submits the consolidated report to Director General no later than 10am on the same day.
10. Only the DG or his designate is responsible for announcing the COVID-19 results to the public.
11. The Laboratory staff completes "Section C" of the COVID-19 Lab Requisition Form and submits to requester following the DG's announcement
12. All COVID-19 positive results should be treated as "critical" and reported to the requester immediately to facilitate isolation and case management. This may be done telephone after subsequent approvals and results released, Documentation of the release of the results will documented including the staff releasing results, date, time and the person results released to.
13. When results are transmitted as an interim report, the final report is always forwarded to the requestor by the Laboratory director/designee.

12.1 Appendix 8 - Laboratory Quality Management System (QMS) guidance for COVID -19 Testing in Kenya

The purpose of this system is providing QMS guidance for COVID-19 testing laboratories to ensure reliability and accuracy of results while ensuring biosafety requirements are met. The guidance provides information on basic QMS requirements for a testing laboratory to produce actionable test results. The QMS measures envisaged here are standard and will apply to laboratories testing for SARS-CoV-2.

As QMS problems may lie anywhere along the path of workflow, procedures will need to be checked within the three phases; pre-testing, testing and post testing. This guidance is subject to revision as new laboratory guidance, knowledge and testing technologies evolve.

Documents

Testing laboratories tasked to conduct testing for COVID-19 must have the following documents/guidance/manuals/SOPs/job aids:

- i. An updated quality manual in place for accredited labs
- ii. A COVID 19 laboratory assessment report following a needs assessment for the testing labs and documentation of addressed non-conformities.
- iii. Updated SOPS for COVID-19 testing sample acceptance criteria
- iv. Updated SOPS for COVID-19 testing that are aligned to the testing method in use
- v. SOPs for sample management and results reporting aligned to the MOH guidance (see Appendix 4.5)
- vi. Updated Biosafety manual within the context of COVID-19 testing
- vii. Evidence of participation in QA/EQA with reference labs
- viii. Operator manuals for main equipment and evidence of their maintenance schedules

Lab personnel

The personnel designated to conduct testing for SARS-CoV-2 must meet the following requirements:

- i. Adequate in number and competently trained to meet the COVID-19 testing demands
- ii. There must be designated trained quality and biosafety officers
- iii. Taken biosafety refresher training with focus on COVID-19 IPC; specimen collection, reception, processing, testing and waste management
- iv. Attend regular meetings to discuss and manage risks perception and ascertain their well being
- v. Have updated vaccinations records.

Testing Equipment

The equipment and accessories used for SARS-CoV-2 testing should meet the following requirements:

- i. Verified and documented performance evaluation records
- ii. Calibrated for optimal performance
- iii. Documented and up to date maintenance as per the manufacturer's manual
- iv. Equipment trouble-shooting SOPs as per operator's manual

- v. Service and repair contracts for the equipment plus additional preventive maintenance plans

Testing Reagents

To ensure that test reagents/kits used for SARS-CoV-2 testing are of good quality in terms of integrity and reliability, the laboratory management will ensure that:

- i. All the testing reagents shall be received from the centrally pre-qualified sources (in this case KEMSA or supporting partner agencies)
- ii. The laboratory must have proper and adequate storage space and conditions for reagents as per manufacturer 's instructions (including cold chain reagents)
- iii. The lab must keep an Inventory of reagents and kits indicating the lot numbers, expiry dates, quantities (kits or test #) and dates received.
- iv. The labs should establish a pass or fail acceptance criteria for all the reagents and kits.
- v. The lab should label reagents or kits that are in use with the date they are opened and put into use, and discarded at the expiration date

Lab process management

To ensure that samples received for testing are appropriate, internal quality control measures are in place, and test result are verified before release the laboratory will do the following:

- i. Implement a criterion for specimen acceptance/rejection to guarantee quality of results
- ii. Verify details on the specimen to match the standardized specimen requisition form
- iii. Prior to embarking on testing any patient samples, labs should run negative and positive verification panels as provided by NPHL which will be evaluated for concordance
- iv. Run both positive and negative controls in every test run to monitor the effectiveness of test procedures
- v. Participate in the nationally coordinated EQA scheme and inter-lab EQA scheme with NIC to assure both competence and confidence of the testing staff.

Management of results

Whatever the system used to management laboratory testing results for SARS-COV-2, the laboratory shall put in place a laboratory information system that is effective for accessibility, accuracy, timeliness, security, confidentiality and privacy of patient information. To achieve these the lab shall:

- i. Sign a confidentiality agreement for keeping confidential and anonymous any personal identifiers of patients
- ii. Verify all the test results before release, these can be done both internally and/or externally with a peer lab
- iii. Follow the guidelines results reporting as per the official reporting protocols (see appendix 5)
- iv. Use LIMS-for sample accession and reporting of results to reduce transcription errors and inputting to the national dashboard

Facility and Biosafety Needs

- i. The laboratory will put in place standard biosafety measures based on safety concerns raised from the initial risk assessment
- ii. The staff must have the following PPE-- use of surgical mask/N95, gloves, goggles or protection shield, waterproof aprons, regular decontamination of surfaces-waste disposal procedures based on biohazard risks at all times.
- iii. The labs must put in place COVID-19 waste management practices as per the provided MOH guidelines and general biohazard risk and levels (refer to the National Waste Management Guidelines and the Biosafety and Biosecurity Refresher Training for Laboratory Personnel in the context of COVI-19
- iv. The laboratory will use certified Class II biosafety cabinets (BSC II) to perform: aliquoting and/ or dilution of specimens, performing serological diagnostic tests, and nucleic acid extraction procedures
- v. The laboratory manager and the QA officers shall be responsible for the implementation and enforcing of quality standards in the testing laboratories.

12.2 Appendix 9- COVID-19 Laboratory Testing Quality Indicators

Following the emergence of SARS-COV 2 pandemic, several test kits have been developed and deployed globally for laboratory confirmations of COVID-19 infections. In Kenya, these test kits are being used in several laboratories that employ different laboratory testing platforms and techniques. A **verification** test is required to demonstrate the performance specifications established by the manufacturer are being met in the testing laboratory. In other instances, a **validation** test is required to demonstrate that the performance specifications established by the manufacturer are being met despite modification of the protocol by the testing laboratory. These changes include use of different testing reagents or testing equipment.

This has raised the need to guide laboratories on establishing standard quality measures to ensure COVID-19 test results from each laboratory are accurate and reliable. This chapter outlines quality indicators that allow the quantification and monitoring of quality in the COVID-19 total testing process to help laboratories to identify and eliminate errors. Below is the list of quality indicators:

- i. Assay verifications/validations
 - ii. Confirmatory testing
 - iii. Proficiency Testing
 - iv. Quality control monitoring
 - v. Kit lot to lot verifications
6. Verifications/Validations of COVID-19 Assays
- a. Verification/validation of an assay is done before adopting the protocol for testing of patient samples.
 - b. To verify an assay, the test should be run as directed in kit insert; to validate an assay, the test should be run according the laboratory's modified protocol.
 - c. All new COVID-19 testing laboratories are required to run verification samples before receiving MoH approval to test.
 - d. A minimum of 20 analytes are be analyzed; 10 positives and 10 negatives.

Note: For safety purposes, laboratories are strongly advised to use non-infectious or inactivated materials (Positive controls). Positive samples are NOT to be used unless they have undergone inactivation to render the sample non-infectious (refer to SOP on COVID-19 Laboratory testing workflow)

7. Documentation of verification/validation data should include the following information:
- a. Purpose of verification/validation.
 - b. Kit name and lot numbers used
 - c. Assay method (unmodified/modified)
 - d. Number of controls (negative and positive) tested per kit.
 - e. Test results
 - f. State any discrepant result and outline how it was investigated.
 - g. State a conclusion of whether the new method is acceptable for use.
 - h. Name of lab personnel performing the test
 - i. Submit the results to the QAO/lab manager/designee for approval.

8. Verification results should be submitted to NPHL before commencement of testing patient samples.

9. Confirmatory Testing

Results confirmation will be done through inter laboratory comparison. This consists of testing the same samples by different laboratories and comparing the results to assess the reliability of the test results of the participating laboratories. This method evaluates inter-laboratory agreement and technical errors but does not evaluate accuracy.

5. For a laboratory that requires to be approved for testing for COVID- 19 the following requirements will be followed:
 - a. The laboratory will apply to the Director General of Health stating the willingness and capacity to test.
 - b. The Director General of Health will constitute a technical team that will assess the laboratory utilizing the WHO checklist on the competence of a Covid19 testing laboratory.
 - c. The technical team will conduct the assessment deploying the WHO checklist and prepare a report. The report will advise the DG whether the laboratory meets the requirements or not. The laboratory will additionally analyze 20 samples (10 positives and 10 negatives) from an already approved laboratory and have 100% concurrence and share that report with the Director General of Health.
 - d. The Director General of Health will on the basis of the technical report and the performance of the peer testing either approve or deny approval of the laboratory.
6. All newly approved COVID 19 testing laboratories will be required to:
 - a. Test the first twenty (20) COVID-19 suspect samples in parallel with an existing approved COVID-19 testing laboratory to verify that their output is reliable. This will be done until consistency is ascertained, following which they are given clearance to test on their own.
 - b. Subsequently enroll into external quality assessment scheme via the National Influenza Centre.
7. All MOH approved COVID-19 testing laboratories will be required to submit the first 10 positives and 10 negative samples to NPHL for verification on a monthly basis.
8. All samples with presumptive positive result should be retested using the same platform. If the result is still presumptive, the laboratory should submit the sample for confirmation to a laboratory designated by NPHL. (see Appendix 4.7).
9. In order to test check for efficiencies of downstream processing and staff competencies, the laboratory manager or his/her designee will randomly select three (3) previously tested samples, blinded to the testing staff, for repeat testing on a weekly basis. A corrective action plan will be instituted should there be a failure to get the expected result
10. Documentation of inter-laboratory results should include the following information:
 - i. Name of initial testing laboratory and date of initial test
 - ii. Kit name and lot numbers used for initial testing and NPHL testing
 - iii. List of samples included in inter-laboratory testing.

- iv. Results of inter-laboratory testing
- v. Statement of any discrepant result and outline of how it was investigated.
- vi. Conclusion of whether the inter-laboratory results are acceptable or not acceptable.
- vii. Name of lab personnel performing the test
- viii. Submit the results to the Laboratory manager/designee for approval before final review by NPHL laboratory director.
- ix. Submission of result to initial testing laboratory

11. Proficiency Testing

Proficiency testing (PT) is a form of external quality assurance which evaluates the ability of a laboratory to produce test result within acceptable performance criteria. This involves an external provider sending unknown samples for testing to the testing laboratories and comparing the results to assess the reliability of the test results of the participating laboratories. Given the sensitivity of the COVID-19 results to patient management COVID 19 testing will receive blinded samples from NPHL for assessment at least quarterly. Root cause analysis and corrective interventions for all failed runs should be done and documented in a timely manner and appropriate changes and improvements undertaken.

14. COVID-19 Assay Quality Control Monitoring

The overall approach in quality control program consists of analyzing patient specimens along with specimens of known concentration ("controls") and carefully recording and interpreting control values before reporting patient results.

The COVID-19 laboratory tests must be performed as follows:

- a) The laboratory shall draft an SOP based on the kits used to test for COVID-19 and specify the number of controls run for each test (if more than one control is run)
- b) An extraction control (blank sample) is included at an interval predetermined by the laboratory, to detect any contamination of the lab testing process
- c) The laboratory must ensure that scheduled maintenance and instrument calibration checks are done according to manufacturer's recommended procedure
- d) All laboratory tests for COVID-19 patient samples must be run with controls. They are run and analyzed at the same time and in the same manner as the patient specimens
- e) Every laboratory performing COVID-19 testing must prepare control logs and control charts to monitor the performance of controls with every test run. Failed controls invalidate the patient test results and the latter should not be reported.

Note: See appendix for sample of control logs and charts

- f) Identify out-of-control results and take appropriate action
- g) Document corrective actions and root causes for the failed controls

- h) Repeat the test for samples and controls from the failed test run
- i) Record both control values. If the repeat control run falls within acceptable limits (as per protocol cut off and control charts- see appendix) the patient results may now be reported. If controls fail, **DO NOT** report patient results
- j) When a control fails, the laboratory supervisor/designee may increase the number of controls, frequency of controls or requests outside testing.

All quality control results must be documented including any out-of-range results.

15. Lot to Lot Kit Verifications

Performance of lot to lot verifications of COVID-19 test kits ensures consistent and correct results when using kits or reagents from different batches while monitoring any result variations obtained from the laboratory due to reagent changes

- a) New lots of primers/control material/kits must be assayed in parallel alongside the lots currently in use.
- b) Test method must be the same
- c) Twenty (20) values of controls (10 positives and 10 negatives) are used in the lot verifications

Note: For safety purposes, laboratories are strongly advised to use **non- or inactivated materials** (Positive controls). Positive samples are **NOT** to be used unless they have undergone inactivation to render the sample non-infectious (refer to SOP on COVID-19 Laboratory testing workflow)

14. Documentation of verification data should include the following information:

- i. Kit name used in lot to lot verification
- ii. Lot numbers being verified
- iii. List of controls (negative and positive) tested per kit and the test results
- iv. Calculation of kit accuracy

New lot = 9 positives, 10 negatives

Current lot = 10 positives, 10 negatives

% positive accuracy ($9/10 \times 100 = 90\%$)

%negative accuracy ($10/10 \times 100 = 100\%$)

Total accuracy ($19/20 \times 100 = 95\%$)

An accuracy result of $\geq 80\%$ is acceptable for the laboratory

- A. State any discrepant result and outline how it was investigated.
- B. State a conclusion of whether the new lot number is acceptable for use.
- C. Submit the results to the QAO/lab manager/lab supervisor for approval.

15. Sample Quality Control Documents

The documents below may be adopted by testing labs for daily use in quality control activities.

Quality Control log

QUALITY CONTROL LOG					
TEST					CONTROL LOT NUMBER:
					TEST KIT LOT NUMBER:
DATE	CONTROL VALUE	PERFORMED BY	ACCEPT	REJECT	CORRECTIVE ACTION TAKEN:

16. Quality Control chart

- Control chart is prepared by calculating the mean and standard deviation of a minimum of 20 values tested using the COVID-19 assay
- Mean – The average of all control results
- Standard deviation – The statistical measure of how much the results vary from the mean value.
- Calculation of $\pm 3SD$ is useful in defining the acceptable limits for control tests.

$$+3SD = \text{Mean} + (SD \times 3)$$

$$-3SD = \text{Mean} - (SD \times 3)$$

The mean, Upper limit ($+3SD$) and lower limit ($-3SD$) are placed on a line graph and the individual control performance are charted within the graph as displayed in example below:

- This chart is used to monitor performance of the control within acceptable limits
- Interpretation: Any control charted above $\pm 3SD$ is to be investigated
- Laboratory staff should monitor the control chart performance a trend – a gradual increase of control performance. This could be as a result of deterioration of the control or other testing reagents.
- Laboratory staff should monitor the control chart performance a shift – an abrupt change (either increase or decrease) that be result from introduction of a change (Change in test kit, change in instrument function or technique employed by lab staff.

13 References

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