

REPUBLIC OF KENYA



**MINISTRY OF HEALTH**

**COVID-19 Antigen Rapid Diagnostic Testing  
Interim Guide**

**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

Fast, 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, testing 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.

The World Health Organization has expanded the listed tests to include antigen rapid diagnostic tests. However, the accuracy of antibody detecting tests as clinical diagnostic tools has not been well established and requires further studies. The appropriate application of these tests varies depending on the goal of testing and stage of disease. For the diagnosis of active SARS-CoV-2 infection, RT-PCR tests are the current reference diagnostic standard in use in Kenya. This guide introduces the use of Antigen rapid tests for COVID-19 diagnosis and surveillance while continuing to evaluate other immunodiagnostic assays for future use. This document will be revised as new scientific evidence and knowledge is available.

This guide 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 and the increasing number of COVID-19 cases. The guide 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 guide. The Ministry of Health is grateful to all of them for their concerted effort to develop the guide 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.

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**Dr. Francis Kuria**  
**Ag. Head, Directorate of Public Health**

### 3 Introduction

The Coronavirus 2019 (COVID-19) pandemic was first reported on 31<sup>st</sup> December 2019 in Wuhan City, Hubei Province, China. By 29<sup>th</sup> November 2020, **61,869,330** cases and **1,448,896 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 **eighty-three thousand, three hundred and sixteen (83,316)** confirmed cases of COVID-19 including **one thousand, four hundred and fifty-two (1,452)** deaths (CFR 1.7%) by 29th November, 2020. The index case was confirmed on 13th March 2020. Health care workers have not been spared with **two thousand seven hundred and twenty-seven (2,727)** health care workers diagnosed and **thirty-one (31)** deaths recorded by 29<sup>th</sup> November, 2020. 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, travel restrictions and limitations on gatherings to further reduce the spread of COVID 19 in the country.

Since the beginning of the outbreak, WHO has emphasized the importance of testing. Between September and November, 2020 last quarter, Kenya has recorded an exponential increase in COVID-19 confirmed cases and deaths. Evidence shows an established widespread local transmission in the country (98% 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 identified high risk populations such as contacts and isolation of positive persons.

In the recent weeks, Kenya has increased her testing capacity resulting in identifying more numbers of positive cases of COVID-19. All forty-seven (47) counties are now experiencing community transmission. 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 guide to include the use of point of care tests antigen rapid test kits. The guide 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 guide is to define the use of available COVID-19 tests in Kenya in order to advise on the resource planning and effective strategies to interrupt COVID-19 transmission in the country. The guide

- a. Describes the various tests in Kenya
- b. Defines those who will benefit from the various tests
- c. Advises on the interpretation and use of the antigen rapid diagnostic test results
- d. Provides a testing algorithm for COVID-19
- e. Stipulates the requirements for adoption of an antigen rapid diagnostic test in Kenya

#### **5 Current testing strategy in place COVID-19 Tests in Kenya**

By June 2020, the country noted an increase in mass COVID-19 testing however, the existing capacities for testing had been unable to match the demand for testing. This demand for testing hampered by a perennial shortage of reagents that threatened even the prioritization of confirmatory testing of suspected cases. The demand for a balanced cost-effective testing strategy necessitated the employment of a well-targeted structured escalation of testing that would generate information to be used for evidence-based response activities. This current strategy targets the following groups:

- i. All individuals meeting current MOH case definition a definitive diagnosis will be required for purposes of focused management
- ii. All individuals presenting to a health facility with symptoms of upper or lower respiratory tract infection AND who also fulfil the 3 ‘Suspect criteria’
- iii. All health care workers who meet case definition or who present with symptoms of respiratory infection.
- iv. 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.

- v. All close household contacts of confirmed cases. (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)
- vi. 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 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.
- vii. 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
- viii. 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)

## **6 COVID-19 testing Technologies in Kenya**

The following tests are available for use in Kenya:

### **6.1 RT PCR tests**

COVID-19 Coronavirus Real Time PCR in Vitro Diagnostic assay relaying on fluorescent PCR technology and aiming at qualitative detection of SARS-CoV-2 from upper and lower respiratory tract specimens. Upper respiratory tract specimens include throat swab and nasopharyngeal swab. Lower respiratory tract specimens include sputum. Sampling objectives include suspected cases infected by SARS-CoV-2, suspected cases due to crowd gathering. The World Health Organization (WHO) recommends that a test that meets the minimum performance requirements of at least 80% sensitivity and  $\geq 97\%$  specificity can be used in the country.

### **6.2 Antigen based Tests**

Viral antigen tests check for the presence of SARS-Cov-2 in samples from the respiratory system. Viral tests are recommended to diagnose acute infection of both symptomatic and asymptomatic individuals, to guide contact tracing, treatment options, and isolation

requirements. Some tests are point-of-care tests, meaning results may be available at the testing site in less than an hour. Other tests must be sent to a laboratory, a process that may take at least 1-2 days.

### 6.3 GeneXpert tests

The Xpert Xpress SARS-CoV-2 test is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swab specimen collected from individuals who are suspected of COVID-19 infection. GeneXpert is a 50 min RT-PCR-based assay detects the pan-sarbecovirus E gene and the N2 region of the N gene as its SARS-CoV-2-specific target. The sensitivity of the Xpert Xpress SARS-CoV-2 assay is 100% and the specificity was 80%. Results are for the identification of SARS-CoV-2 RNA. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The Xpert Xpress SARS-CoV-2 test is intended to be performed by trained users in both laboratory and near patient testing settings. GeneXpert is used in diagnosis of COVID-19 in persons who meet the case definition.

### 6.4 Antibody tests

These are only in use under research purposes and not yet approved for use in Kenya.

## 7 Adoption of COVID-19 Antigen Testing

The Country relies on reverse transcription polymerase chain reaction (RT-PCR) performed on a nasopharyngeal specimen. This testing method remains the gold standard for detecting SARS-CoV-2 and is characterised by both high sensitivity and specificity in detecting viral ribonucleic acid (RNA). Despite the high sensitivity and specificity of the test, there have been various challenges that have hindered the scale up of this test including the long turnaround time, the distances to the few laboratories with the testing capacity, increase in demand for testing against a global shortage of diagnostic commodities among others. This challenge led to the development of point of care antigen tests which are more user friendly and have a turnaround time of 10 to 30 mins

from the time of sample collection. The World Health Organization recently listed two (2) brands of COVID-19 antigen tests. Kenya plans to adopt the use of antigen testing to ease the of testing challenges. This will be in addition to the RT PCR and GeneXpert testing currently in use in the country.

## 7.1 Justification for the use of Rapid Antigen tests for COVID-19

The country has relied on the use of RT-PCR, which is expensive, available in few high-level laboratories, requires high level of skill and has a long turnaround time. Rapid antigen tests can contribute to overall COVID-19 testing capacity, offering advantages which include shorter turnaround times and reduced costs, especially in situations in which RT-PCR testing capacity is limited.

The sensitivity for rapid antigen tests is generally lower than for RT-PCR, however, WHO has recommended that a test that meets the minimum performance requirements of WHO at  $\geq 80\%$  sensitivity and  $\geq 97\%$  specificity can be used in the country. The use of rapid antigen tests is appropriate in high prevalence settings when a positive result is likely to indicate true infection, Rapid antigen tests can help reduce further transmission through early detection and isolation of infectious cases, enabling a rapid start of contact tracing.

Rapid antigen tests have been developed as both laboratory-based tests and for near-patient use (point-of-care), and results are normally generated in 10 to 30 minutes after the start of the analysis, and at low cost.

## 7.2 Advantages of rapid antigen tests

Rapid antigen tests have shown various advantages such as timeliness of test results, the ease of scalability, the simplicity of use, availability of human and material resources, and overall logistical arrangements for sampling and testing and costs.

Rapid antigen tests can be used for the early detection of cases when RT-PCR testing capacities are not available and receiving timely results is critical, quick identification of infected and infectious contacts and patient triage process in healthcare settings at admission.

Use of rapid antigen tests as a public health intervention would be aimed at meeting the following objectives:

- i. **prompt clinical management** of cases with COVID-19 symptoms at admission

- ii. **control transmission:** early detection of cases, contact tracing, population-wide testing
- iii. **mitigate the impact of COVID-19** in healthcare and social-care settings: triage at admission, early detection and isolation
- iv. **identify clusters or outbreaks in specific settings:** early detection and isolation.

## 8 Uses of Testing technologies

### 8.1 Diagnostic

Diagnostic tests are those tests used to confirm presence of disease. The following tests will be used for the person who meets the definition of case

- a. RT PCR
- b. GeneXpert
- c. Antigen Rapid Diagnostic test

COVID-19 Rapid Antigen Test - A Positive Antigen test will be considered a positive test and isolation, contact tracing and referral to the correct management facility instituted.

### 8.2 Screening

Screening is used to identify COVID-19 infected people in the population who may not be exhibiting symptoms and are without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission. Antigen tests will also be used as a screening test for those without symptoms but have been in contact with a confirmed case. Those that are positive can be confirmed using the RT PCR. Antigen tests will also be used under the following circumstances household contact, contact tracing, outbreaks in special places e.g., prisons, remand, schools, and super spreader events.

### 8.3 Surveillance

Surveillance testing is testing for infection and disease surveillance (surveillance – the routine collection of data about infection/disease distribution; the analysis of those data; and the dissemination of that information to those who need to know). This type of testing, therefore, is aimed at collecting representative data giving insight into the distribution of infection and disease; characterizing data by the essentials of descriptive epidemiology (time, place, person); and documenting epidemiologic trends. In circumstances that the Ministry identifies need for surveillance for the purpose named herein, antigen tests can be used.

Antibody tests when available can be used for surveillance (i.e., IGM and IGM kits) but will not be used for screening or diagnosis. Serology based tests shall be used for epidemiology, when they become available and proven to be useful and cost effective. They are not very useful for acute diagnosis (and remain a preserve for research. Antibody tests have not been listed by WHO or prequalified by FDA and such not approved for use in Kenya

## 9 Who will benefit from the above tests?

***RT PCR is the Gold standard for COVID-19 testing.*** Therefore, the antigen rapid tests will be applied based on the following criteria.

Antigen rapid tests will be used in the following populations

- i. **High prevalence settings-** In this setting, the prevalence is high with a high positive predictive value. The population groups targeted for testing in these settings are:
  - a. Persons who meet the criteria for case definition
    - i. Symptomatic
    - ii. Immediate household and workplace contacts
  - b. Health care workers
    - i. At highest-risk areas
      1. ICU
      2. Isolation facilities
    - ii. Rapid Response Teams
    - iii. Staff working at the laboratory, both laboratory and support staff
    - iv. Staff working at the Accident and Emergency – both technical and support staff.
  - c. Outbreak investigations in congregate settings with super spreader events such as
    - i. Schools and colleges
    - ii. Prisons
    - iii. Gatherings such as religious and political events
  - d. At Prisons and Remand  
A person going into remand or prison should be tested before mixing with others in the premises as they pose a risk of infecting a whole prison which is a closed community with potential for catastrophic outcomes.
  - e. High risk clients in health facilities
    - i. In-patients
    - ii. Patients before surgical procedures
    - iii. Patients seeking dental services

*Health facilities are expected develop priority criteria for OPD clients based on risk*

- ii. **Low prevalence settings** – Antigen rapid diagnostic test will also be used in setting with no access to RT PCR testing (WHO, 2020)
  - a. At the points of entry for arriving passengers
    - i. If they have symptoms of COVID-19
    - ii. Whose COVID-19 certificates have expired
  - b. Special populations such as
    - i. Street families with symptoms or contact with a confirmed case
    - ii. Homes for the elderly
    - iii. Homes for vulnerable children
- iii. Surveillance – Antigen rapid test will be used based on program needs. In this population, a negative test result does not eliminate the possibility COVID-19 infection.

**NB.**

*People departing from the country – (travellers) should be tested using RT-PCR as per host country requirements.*

*There should **be a consultation** among the **East African Countries** on the use of rapid antigen test for ground transportation.*

## **10 Requirements for COVID-19 Rapid Diagnostic Kits for use in Kenya**

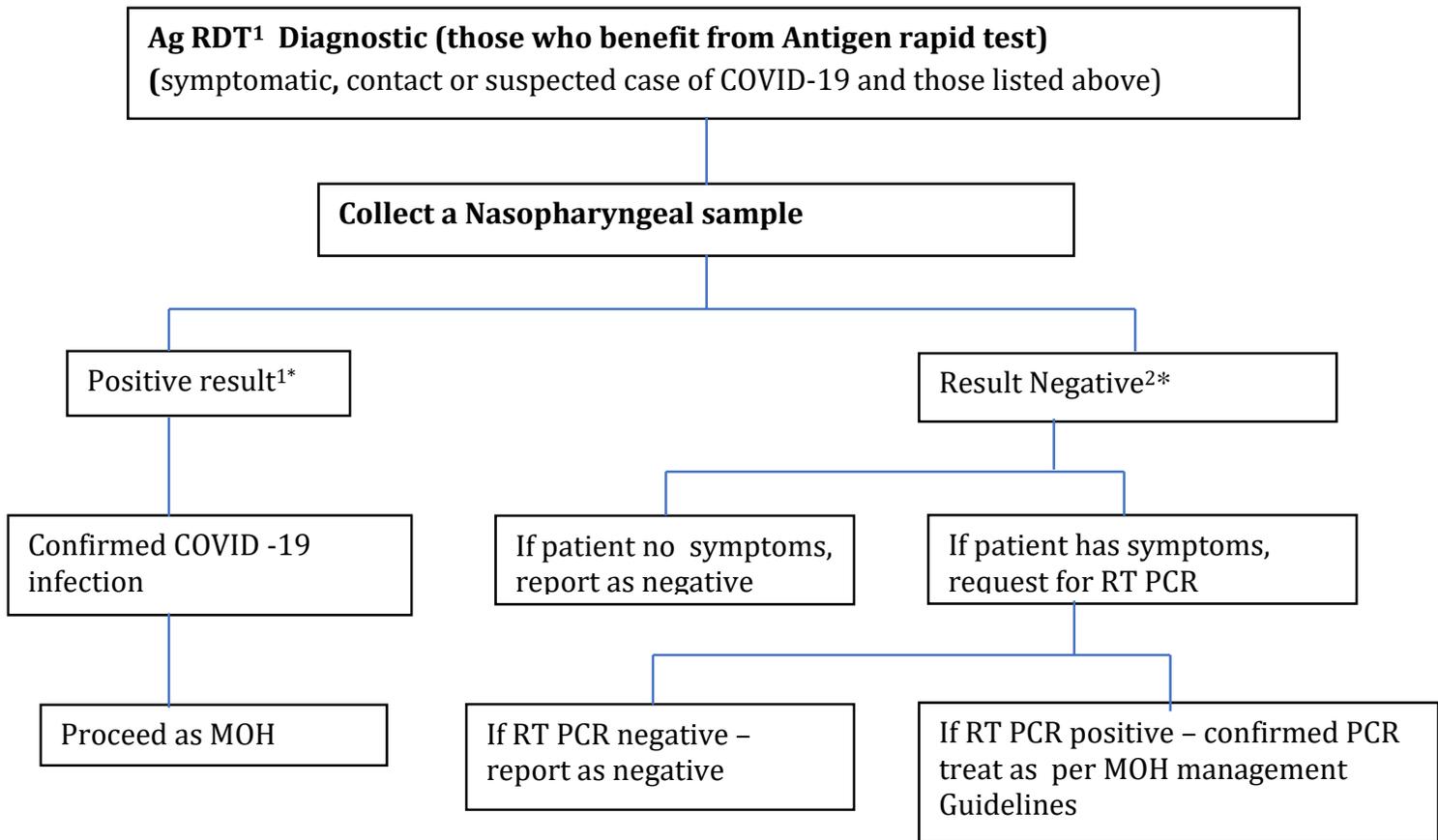
For an antigen rapid diagnostic test to qualify for use in this country, it should meet the following requirements:

1. Must be WHO listed and in use in country of origin
2. Must be validated in country by KMLTTB
3. Must be registered in country by PPB
4. Must have a sensitivity of at least 80% and specificity of over 97% (ref. WHO emergency use listing guidance)

## **11 Recommended Specimens whiles using antigen rapid diagnostic test**

Nasopharyngeal samples will be collected for Antigen based test as per the manufacturer's guidance

## 12 Testing Algorithm



*Algorithm for Rapid Antigen Diagnostic Test*

## 13 Reporting of a positive Case/Interpretation of a Test

- 1 <sup>1\*</sup>A positive test should be considered positive whether the person is symptomatic or asymptomatic (CDC, 2020)
  - a. A positive antigen test in a symptomatic person and/or a person who fits the case definition of a COVID-19 case should be considered as a laboratory-confirmed case and reported as such.
- 2 <sup>2\*</sup>In the event that a rapid antigen test result is negative, and the patient has symptoms of COVID-19, request for a confirmatory RT PCR
  - a. If confirmatory RT-PCR remains negative, the RT PCR is considered over the rapid antigen tests and hence this case is reported as a negative test.
  - b. If confirmatory RT PCR is positive, treat the person as a confirmed COVID-1p patient.

## 14 Who should do the tests

1. Self-testing using the Antigen rapid test is **NOT PERMITTED**
2. Only qualified registered and licenced medical laboratory officer will carry out this test.

## **15 To which facilities will these tests be deployed?**

1. Antigen testing can be deployed at all levels (both registered public and private) up to the dispensary level.
2. Priority is given to high volume health facilities that meet the prerequisite infection prevention and control standards, and have proper waste management systems

## **16 Training and quality Management**

The officers carrying out the tests should be trained on the following

1. Sample collection and handling
2. Testing and reporting
3. Biosafety and Biosecurity
4. Quality Assurance
5. Data management and Communication

## **17 Quality Assurance**

Quality assurance measures should include

- I. Adherence to manufacturer's guidance
- II. National Public Health Laboratories (NPHLs) through the EQA mechanisms shall monitor countrywide quality of antigen testing as per the MOH QA guidance on COVID-19 testing
- III. Post market surveillance of the kits should be a continuous process

## **18 Reporting**

All laboratories or COVID-19 testing site must report rapid antigen diagnostic test or screening results to the MOH/NPHL COVID 19 DATA Centre in accordance with the MOH COVID 19 guideline which requires "every laboratory that performs or analyses a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results of each such test.

1. The report should specify the test used.
2. Both positive and negative rapid **Antigen** diagnostic or screening results must be reported.

Laboratory and testing personnel should collect and report complete patient demographic information and ensure that antigen test results are reported using the proper reporting tool provided by MOH as guided in the attached report submission.

Additionally, all laboratories or testing site must report antigen test results to the individual or the individual's healthcare provider according to the instructions for use of the MOH-authorized SARS-CoV-2 in vitro diagnostic that was used.



## **19 Reference**

1. ECDC, Nov 2020. Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK 2020, UK
2. CDC, 2020. Interim Guidance for Antigen Testing for SARS-CoV-2, USA
3. WHO, 2020. Diagnostic testing for SARS-CoV-2: Interim Guidance