



MINISTRY OF HEALTH
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12th February 2021

All County Directors of Health
All Chief Executive Officers – Private Hospitals
All Chief Executive Officers - Faith Based Organizations
All Chief Executive Officers - Private Laboratories

RE: CIRCULAR ON USE OF ANTIGEN RAPID DIAGNOSTIC TESTING FOR SARS-CoV-2 (COVID 19)

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. Fast, efficient and timely COVID 19 testing is critical in preventing transmission and slowing down the spread of SARS-CoV-2. Since the onset of COVID-19 pandemic in Kenya, the Ministry of Health has entirely relied on PCR-based testing for diagnosis of suspected cases. However, the World Health Organization (WHO) has recently listed two SARS-CoV-2 antigen tests that can be used for COVID-19 testing with appreciable accuracy. In order to adopt the use of COVID-19 antigen kits in Kenya, the Ministry developed interim COVID-19 Antigen Rapid Testing Guideline in Kenya in December, 2020.

The guideline outlines the circumstances and the populations on which these tests can be used. The guidelines also summarize interpretation of expected results when using rapid antigen tests. As mentioned in the guidelines, PCR remains the reference diagnostic test for COVID-19 and for now, it is the only type of test acceptable for people who require a COVID-19 certificate before travel outside the country.

Prior to testing for COVID 19 testing facilities intending to conduct Antigen testing are required to strictly adhere to the guidance below,



1. The only diagnostic antigen kits that can be used in any testing facility in Kenya are those that are already been prequalified by Stringent Regulatory Authorities (SRAs) such as the World Health Organization (WHO) and the United States Food and Drug Administration (FDA) the full list of RSAs can be obtained from <http://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs>

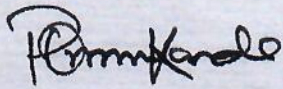
In addition, such kits **Must;**

- a. Be in use in the country of origin
 - b. Be validated in the country by Kenya Medical Laboratory Technologist Technicians Board (KMLLTB).
 - c. Be registered in the country by Pharmacy & Poison Board (PPB).
 - d. Have a sensitivity of at least 80% and specificity of over 97% (ref. WHO emergency use listing guidance).
 - e. Be approved for use in the country by the Ministry of Health
2. All the testing facilities must be assessed and registered by KMLTTB.
 3. All testing facilities that intend to test for COVID-19 using either the antigens kits or PCR or both must seek a written approval from the Director General for health. Laboratories that are already approved for testing and reporting COVID-19 samples using PCR need not apply for a new approval.
 4. All new testing sites must enroll in an external quality control assessment administered by the National Public Health Laboratory (NPHL).
 5. All testing facilities must meet biosafety and biosecurity standards, including waste management and IPC measures.
 6. All testing facilities intending to start antigen testing must provide proof, to the Director General for Health, that their staff have been trained for antigen testing.
 7. All testing sites must have a robust ICT capacity to allow near-real-time submission of results to the Ministry of Health through the National COVID 19 Data Centre domiciled at the NPHL.
 8. Newly Approved laboratories will receive an access code to allow them to submit their results through the NPHL portal while testing facilities that are already approved for PCR testing may continue using the same NPHL portal for reporting the antigen test results.
 9. The interpretation of rapid antigen test results must be done as outlined in the Ministry of Health guidelines on rapid antigen tests.
 10. All results, both positive and negative, must be reported to the NPHL portal.
 11. A reporting tool for Antigen testing shall be shared with all the laboratories approved to conduct rapid antigen testing.



12. All testing facilities must make arrangements to get a PCR-based test for samples obtained from patients with known COVID-19 symptom but who turn negative for the antigen test.
13. All testing laboratories must keep a test register showing the number of patients tested, their metadata, contact details and test results. In order to safe-guard patient privacy, the test register must be confidential and only accessible to people directly involved in COVID-19 testing.
14. Tests performed using test kits received from Ministry of Health or from the government or from other donors must be done free of charge.
15. All new and potential testing sites are directed to familiarize themselves with the rapid antigen testing guidelines published on the Ministry of Health website.

The purpose of this circular is to direct you to bring this information to all the relevant officers under you.



Dr. Patrick Amoth, EBS
AG. DIRECTOR GENERAL

Copy to: Chief Executive Officer, Pharmacy and Poison Board
Registrar Kenya Medical Laboratory Technologist Board
Chief Executive Committee members for Health
Chief Executive Officer- Kenya Health Federation ✓



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