REPUBLIC OF NAMIBIA

MINISTRY OF HEALTH AND SOCIAL SERVICES

Ministerial Building
Harvey Street
Private Bag 13198
Windhoek

OFFICE OF THE EXECUTIVE DIRECTOR

Tel: 203 2334
Fax: 264 61 226-351
E-mail: Mary.Mataranyika@mhss.gov.na
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Enquiries: M. Mataranyika
Ref: 11/6/1

Circular No. 07.... of 2021

TO: PILLAR LEADS,
REGIONAL DIRECTORS,
MEDICAL SUPERINTENDENTS,
LABORATORY MANAGERS

RE: GUIDANCE ON RAPID DIAGNOSTIC TESTING (RDT) FOR COVID-19 RESPONSE

PURPOSE OF THIS GUIDANCE

This document provides guidance to the Ministry of Health and Social Services (MoHSS), laboratory personnel and other implementing partners in Namibia on the application of RDT to COVID-19 testing. The guidance serves as reference for policymakers, laboratory, implementing partners, and experts on use case scenarios and associated testing algorithms for COVID-19 RDT. It recommends the use of antigen and antibody tests to increase access to testing and enable timely results release for persons with or without symptoms in specific settings.

BACKGROUND

The Coronavirus disease 2019 (COVID-19) which is caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has impacted heavily on global health and Namibia is no exception. Since the beginning of the pandemic, the country relied on real-time Reverse Transcription Polymerase Chain Reaction (rRt - PCR) for testing to diagnose people infected with SARS-CoV-2. Due to the challenges of rRt-PCR such as high-cost, technical expertise and long results turnaround times (TATs), RDTs are being considered by other countries because they are rapid, inexpensive and scale-up the testing capacity.

Namibia remains one of the countries with an active approach to fighting the pandemic and steadily continues to improve. This is evident in the increased testing capacity from initially one (1) testing laboratory to six (6) authorized laboratories currently testing for COVID-19. Expansion of testing to more laboratories is ongoing.

NAMIBIA COVID-19 TESTING STRATEGY

Namibia, like many other countries is planning to implement the use of the RDTs to assist in expanding the testing capacity and improving the test results TAT. Each country is encouraged to design a testing plan that fits the country's COVID-19 situation, in line with the WHO standards.

There are two types of COVID-19 RDTs: antigen (Ag) tests which directly detect SARS-CoV-2 viral antigen(s) and antibody (Ab) tests which detect one or more types of antibodies against the virus produced by the host immune response system. RDTs can be used outside of laboratory conditions, such decentralized settings at/or near the point of care (POC). Ag-RDTs can be considered as alternatives to Nucleic Acid Amplification Tests (NAAT) for direct detection of SARS-CoV-2 virus in their diagnosis of early COVID-19. COVID-19

The plan is to make use of SARS-CoV-2 Ag- RDT where there is widespread community transmission of COVID-19, especially in congregated settings, such as educational institutions, clinical settings, correctional facilities or in scenarios where it is not possible to test all suspected cases by molecular testing methods in time to detect, isolate and trace contacts. To ensure the quality of tests results, the use of normal and abnormal quality control reagents should be implemented as stipulated in the user manual in-set.

Only validated methods that have been verified for use in Namibia shall be deployed. SARS-CoV-2 Ag-RDTs must meet the minimum performance requirements of ≥80% sensitivity and ≥97% specificity compared to an approved NAAT molecular test

WHO recommends these tests to be used in symptomatic individuals and asymptomatic and high-risk close contact with COVID-19 patients in the last 14 days. The Ag-RDTs provides only an initial screening test result.

It may also be utilized in the following specific settings for testing:

- Screening of people in parts of the country where PCR results would be delayed due to distant sample transport.
- Screening of patients due for emergency surgeries and emergency need for admission to urgent care/IC wards.
- Separately, RDTs that detect antibodies can be used to provide sero-epidemiological data useful to determine the magnitude of COVID-19 exposure in our population.
- Screening of travelers at points of entry if they are displaying symptoms.

Nevertheless, a negative result does not necessarily rule out a possible infection, and clinical and epidemiological information should also be considered to guide the implementation of public health measures. If available, molecular testing might be considered for SARS-CoV-2Ag-RDTs negative patients, particularly in priority/high risk patients depending on the clinical and epidemiological criteria.

The SARS-CoV-2 Ab-RDT must only be used for ongoing therapeutic purposes at point-of-care (POC). Antibody test results should not be used to diagnose patients with an active infection. It must be emphasized that an Ab-RDT cannot be used in the absence of an Ag- RDT to obtain a diagnosis. In the absence of an Ag-RDT, diagnosis must be established with a PCR test.

The MoHSS expect that all relevant stakeholders will assist in executing this directive and that our combined efforts will collectively strengthen and improve the health care services and the COVID-19 pandemic response.

The content of this circular should be disseminated to all health care providers in both public and private health sector.

EXECUTIVE DIRECTOR
MINISTRY OF HEALTH AND SOCIAL SERVICES

Ben Nangombe
EXECUTIVE DIRECTOR

Algorithm for using the Antigen Rapid Diagnostic Tests (Ag-RDTs) in Namibia