Telephone: General Lines: 256 – 417 – 712260
Permanent Secretary's Office: 256 – 417 – 712221
Toll Free 0800100066
E-mail: ps@health.go.ug
Website: www.health.go.ug
THIS SUBJECT PLEASE QUOTE NO. ADM.105.261/80

Ministry of Health
P. O. Box 7272
Plot 6, Lourdel Road,
Wandegeya
KAMPALA
UGANDA

2nd June, 2021

District Health Officers,
Hospital Directors, Medical Superintendents,
Health Facility In-Charges
Private Health Facilities
Accredited COVID 19 testing laboratories

Dear all,

RE: GUIDANCE ON THE USE OF COVID 19 ANTIGEN RAPID DIAGNOSTIC TEST (RDTS) IN UGANDA (JUNE 2021)

There is a high demand for SARSCoV2 testing to identify cases, isolate, manage and conduct contact tracing. Furthermore, many countries have imposed restrictions at border crossings requiring travellers to have negative polymerase chain reaction (PCR) tests before entry. This PCR method recommended by WHO as a gold standard diagnostic test is primarily designated for specialized laboratories requiring special training of lab staff, has a longer turnaround time for results, is costly and further complicated by the global procurement challenges.

WHO Interim guidance of 11th September 2020 recommend that SARS-CoV-2 antigen (Ag) RDTs that meet the minimum performance requirements of ≥80% sensitivity and ≥97% specificity compared to a Nucleic Acid Amplification Tests (NAAT) reference assay can be used to diagnose SARS-CoV-2 infection in a range of settings where NAAT is unavailable or where prolonged turnaround times preclude clinical utility. However, antigen tests have limitation of sensitivity, especially in the presence of low viral loads.

Ag-RDTs are most likely to perform well in patients with high viral loads which usually appear in the pre-symptomatic and early symptomatic phases of the illness (within the first 5-7 days of illness) for those with symptoms, however, asymptomatic individuals can also have high viral loads in the early days of infection. In Uganda, all new testing kits introduced to the Uganda market must undergo an in-country laboratory verification at UVRI, a designated national, WHO and Africa CDC SARSCoV-2 reference laboratory, before being recommended to the Ministry of Health (MOH) for use in the country.

UVRI has recommended use of the **Standard Q (by SD Biosensor) and Abbott PanBio** that reached the WHO recommended performance and they have now been recommended for use as COVID-19 diagnostic intervention by MOH, in a phased approach as we gain more experience in their use, allow confidence

52

building, continuous field evaluation and additional data generation. So far, the field evaluation of Abbott PanBio has been concluded with data that

concurs with the initial laboratory evaluations and field evaluation for Standard Q is underway.

Following this, MOH came up with the following recommendations:

These antigen RDTs to be used for rapid screening of the following population.

- Symptomatic alerts and symptomatic contacts of confirmed cases.
- Patients with COVID -19 like symptoms presenting at health facilities.
- Symptomatic cases in congregate settings like prisons and schools suspected to be exposed to known case/s and at high risk to establish the outbreak.

These recommendations were made mindful that not only symptomatic patients have high viral loads but in order the manage these symptomatic patients without delay waiting for PCR results.

Furthermore, MOH recommends that:

- Any RDT positive cases from the abovementioned population will be considered "COVID - 19 positive" and managed accordingly not requiring additional PCR confirmation except in special cases such as genomic sequencing or routine quality control monitoring.
- Any RDT negative case with highly suggestive symptoms will be considered "suspect COVID - 19" case until confirmed negative by PCR and should be managed with enhanced infection, prevention controls (IPC).

The laboratories at these Health units will take off an additional specimen for those clients who are antigen negative but with symptoms to be sent for PCR testing.

RDT results should be uploaded to result dispatch system (RDS) using the different systems the ICT team has set up in the different facilities.

No approvals have been given for use of any other antigen RDTs in COVID 19 diagnosis apart from the above and currently no payment should be made for any government-issued Antigen RDT tests.

Dr. Charles Olaro
FOR: DIRECTOR GENERAL HEALTH SERVICES

Cc: Hon. Minister of Health
Cc: Permanent Secretary
Cc: All Directors - Ministry of Health
Cc: All Commissioners - Ministry of Health