



Report of Africa Medical Devices Forum COVID-19 Task Force

5 -15 MAY 2020

1. Introduction

AMDF Covid -19 Task Force through its working groups have been conducting discussions and developing series of documents from 6th April to 20th May 2020. To date, three reports have been developed and submitted to the AMRH SC, endorsed and later on shared with Regulators for the purpose of addressing some of the challenges that have been reported by NRAs.

2. Working group 1: List of COVID -19 diagnostic and surveillance tests

The group updated the COVID-19 Nucleic Acid tests to include assays which were recently listed for Emergency Use by WHO Diagnostics Prequalification,

United States Food and Drug Administration (US FDA), Nigeria Centre for Human Virology and Genomics and Uganda (Annex 1). Included in the list is a link to the Foundation for Innovation of New Diagnostics (FIND) showing results of ongoing performance evaluation of commercial NAT assays <https://www.finddx.org/covid-19/sarscov2-eval-molecular/molecular-eval-results/>

In addition, the list of COVID-19 serology assay which have been listed by United States Food and Drug Administration, Therapeutic Goods Administration (Australia), Singapore FDA and Nigeria Agency for Food and Drug Administration (NAFDAC) was updated (Annex 2). **WHO does not recommend used of serology assays for diagnosis of COVID-19.** Therefore, these Serology assays are only indicated for identification of individuals who have been infected by the virus causing COVID-19.

Lastly, the group discussed and provided feedback on a draft performance evaluation protocol for COVID-19 serology assays. The draft protocol is further been improved to include the sample size and the performance criteria of tests under evaluation.

3. Working group 2: List of medical devices and other products for surveillance, prevention control and case management of COVID-19

In global response to COVID-19 pandemic the World Health Organization has published a recommended list of medical devices and personal protective equipment (PPEs) that are critical in supporting other medical and non-medical interventions embarked by the member states. The items are essential in protection of health workers working in the front line in the fight of the pandemic as well as treatment of patients requiring hospitalization as a result of infections from the causative virus.

During the past two weeks WG-2 updated the list of approved WHO COVID-19 priority medical devices and PPEs to include products that have been authorised by the IMDRF countries and Uganda. (Annex 3).

4. Feedback session

Feedback session with AMDF leadership was conducted on 15 May 2020 to receive report from the Chairpersons of the two working groups and the following are the deliberations:

- The list of COVID-19 assays will be updated regularly including a link to results emanating from Foundation for Innovation New Diagnostics (FIND) performance evaluation. They will be shared with NRAs and posted on the AUDU NEPAD, WHO Afro and others.
- The lists will include two important statements

- The lists are for information only.
- WHO does not recommend use of COVID-19 serology assays.

5. List of annexes

- Annex 1: Updated list of COVID -19 NAT diagnostic tests
- Annex 2: List of COVID -19 serology tests.
- Annex 3: Updated list of priority medical devices including PPE

6. Members of various working groups

Working Group 1:

Anafi Mataka (Chair, African Society for Laboratory Medicine), Andrea Keyter (Africa Medical Devices Forum, South Africa Health Products Regulatory Authority), Agnes Kijo (Secretariat, World Health Organization), Paul Tanui (Secretariat - African Union Development Agency, New Partnership for Africa's Development), Sunday Kisoma (Tanzania Medicines and Medical Devices Authority), Donewell Bangure (Africa Centres for Disease Control and Prevention), Adrian Puren (National Institute for Communicable Diseases, South Africa), Rosemary Audu (Nigerian Institute of Medical Research, Nigeria) and Willy Urassa (Advisor)

Working Group 2:

Sunday Kisoma (Chair TMDA, Tanzania), Andrea Keyter (AMDF, SAPHRA, South Africa), Agnes Kijo (Secretariat WHO), Adriana Velazquez (Secretariat WHO) and Willy Urassa (Advisor).

Other members

- AZATYAN, Samvel (WHO HQ Secretariat)
- SILLO, Hiiti Baran (WHO HQ Secretariat)
- KNIJAZKOV, Stanislav (WHO AFRO)
- Margareth Ndomondo-Sigonda (AUDU-NEPAD)