An Africa-focused Report on Safety Data of COVID-19-related Products, May 2020 – Update No. 1
Compiled by AU-3S Team

Introduction

This report highlights safety concerns of some medical devices and household chemicals used for coronavirus disease 2019 (COVID-19) diagnosis and management as reported on the globe and relevant to the African context.

Diagnostics and other medical devices, as well as household chemicals, are within the scope of COVID-19 related products used in Africa and their safety profiles will be characterized through the implementation of the **African Union Smart Safety Surveillance (AU-3S) programme** of the **AUDA-NEPAD.**

Governments across the globe, including Africa, have been committed to increased testing capacity, in recognition of testing as a critical intervention in controlling the virus spread, especially as public restriction measures are revised. This situation has led to the introduction of more COVID-19 tests and a scale-up of company operations to meet demand. Therefore, the required performance evaluation of these products, before being employed for the clinical diagnosis of COVID-19, have been limited.

There are significant advances in *in vitro* diagnostic (IVD) assays for COVID-19. The main IVD assays used for COVID-19 employ real-time reverse transcriptase-polymerase chain reaction (RT-PCR). Other serology immunoassays (IAs) have also been developed that complement the molecular assays. The most prominent IAs are automated chemiluminescent IA (CLIA), manual ELISA, and rapid lateral flow IA (LFIA) for the detection of immunoglobulin M (IgM) and immunoglobulin G (IgG) produced in persons in response to SARS-CoV-2 infection[1].

Diagnostic tests (molecular or antigen tests) can be used to diagnose infection with the SARS-CoV-2 virus. Molecular tests (Nucleic acid tests [NAT] or PCR tests) detect the presence of viral RNA. Most molecular tests have been approved under Emergency Use Authorization (EUA) and based on the currently available data, are highly accurate. This means that a positive or a negative result from a molecular test is likely to be true. Antigen tests detect the presence of viral proteins that are part of the SARS-CoV-2 virus. These tests are often faster and simpler to run, specific for the virus, but are not as sensitive as molecular tests. This implies that a positive result is highly accurate, but there is a higher chance of false negatives; therefore, a negative result does not rule out infection.

Consequently, negative results from an antigen test may need to be confirmed with a molecular test before making treatment decisions or to prevent the possible spread of the virus due to a false negative. Serological (antibody) tests refer to tests that detect antibodies to the SARS-CoV-2 virus. The antibodies are part of the body's immune response to exposure and not the virus itself, so such testing cannot be used for diagnosis of infection. If IgG

antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious[2].

As at 14th May, six (6) nucleic acid testing (NAT) assays were under the WHO Emergency Use Listing for *In vitro* diagnostics (IVDs) detecting SARS-CoV-2 nucleic acid[3]. National Medicines Regulatory Authorities (NMRAs) need to ensure that adequate safety data resulting from the use of molecular tests approved under EUA are collected to enhance the characterization of the product safety profile for COVID-19 diagnosis. This will include proactive and reactive surveillance to scan for potential safety issues and address occurring issues, respectively.

Unauthorized COVID-19 antibody detection RDTs and others

Several regulatory authorities have reported and expressed concerns about the commercial promotion of COVID-19 antibody detection RDTs; including the Ghana FDA[4], Medicines Control Authority of Zimbabwe[5], the European Centre for Disease Prevention and Control (ECDC) and USFDA. ECDC reported several COVID-19 RDT devices with fraudulent documentation, incomplete technical files and unsubstantiated claims, with some of them sold as alleged self-tests ([6]cited in[7]). The USFDA also reported on unauthorized, fraudulent test kits that are marketed to test for COVID-19 in the home[8]. Similarly, WHO has received multiple reports on falsified IVDs and laboratory reagents for the detection of SARS-CoV-2 and issued warnings to this effect[9].

Furthermore, promotional product flyers, email communications and social media adverts that are too optimistic, suggestive and potentially misleading, when advertising COVID-19 antibody detection RDTs are rampant[10]. The Zambian Medicines Regulatory Authority (ZAMRA) noted with concern, reports in some sections of the media about promotion and sale of falsified alcohol-based hand sanitizers[11]. Ghana FDA, NAFDAC and National Drug Authority (NDA) Uganda issued public alerts on illegal distribution and sale of unregistered and substandard (failed alcohol content test) hand sanitizers as well as substandard face masks and other Personal Protection Equipment (PPEs) [12],[13],[14],[15]. National Regulator for Compulsory Specifications (NRCS) of Zambia urged the public to be vigilant when purchasing masks and chemical disinfectants as some can be deadly[16].

Performance requirements

The Uganda NDA instructed manufacturers of substandard hand sanitizers that failed the alcoholic content test and other parameters, to withdraw affected batches from the market until corrective action(s) have been implemented and approved by the authority[17],[18].

USFDA has reported on early data that suggest possible inaccurate results from using the Abbott ID NOW point-of-care test to diagnose COVID-19 reiterating that the test may specifically return false-negative results[19]. Likewise, the Spartan Covid-19 System does not perform as claimed for its intended use in a clinical setting, thereby constituting a risk of false-negative test results. Consequently, Health Canada has issued a product recall, stating that the Spartan Covid-19 System is no longer intended for use in diagnosis and should be for research use only[20].

Safety alerts

Safety alerts/notices were issued on some medical devices and household chemicals used in the control or management of COVID-19. Some of these are highlighted below:

***Naphthalene*:** Ghana FDA issued a public alert on the use of naphthalene for the treatment of COVID-19. The alert informed the public that camphor is an insecticide and produces a toxic gas which repels and kills insects and not a proven treatment for COVID-19. The vapour produced by camphor, when dissolved in hot water, elicits a toxic gas which should not be inhaled under any circumstances. Such inhalation can cause skin and eye irritation, nausea, vomiting, abdominal cramps, and diarrhoea. Other related effects are confusion, excitement, convulsions, severe anaemia and renal shutdown[21].

***Alcohol-based hand sanitizers*:** Alcohol-based hand rub for sanitizing hands may results in a near-invisible flame on hands, which causes first- and second-degree burns[22]. This happens if hands are not properly dry and an electrostatic discharge ignites residual alcohol vapour when a metal surface was touched.

Recommended actions on the safety action notices and information can be accessed here http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/covid-19-safety-alerts/

***All devices used to provide High Flow Nasal Oxygen (HFNO) without in-built transport mode*:** Safety action notice was issued about the interruption of high flow nasal oxygen during transfer[23].

***Blood control (closed system) safety cannula*:** Safety action notice was issued on the possibility of new blood control (closed system) intravenous cannulas not able to decompress a tension pneumothorax[24].

***All haemofiltration systems including machines and accessories*:** Reports of off-label modifications to haemofiltration systems when treating COVID-19 patients leading to serious injury and death were received by UK MHRA. Necessary actions, mainly manufacturers' advice is to be followed during the use of such medical devices. Some of such advice is accessible here
https://www.gov.uk/drug-device-alerts/covid-19-all-haemofiltration-systems-including-machines-and-accessories-serious-risks-if-users-don-t-follow-manufacturer-instructions-for-set-up-mda-2020-013[25].

Next step:
African Governments are promoting increased testing capacity and making efforts to ensure adequate supply and safe/responsible use of medical devices for the management of COVID-19. In tandem, the AUDA-NEPAD, through the AU-3S project, will facilitate the aggregation of COVID-19 diagnostics and medical devices-related safety data, provide a continental repository of such data and develop/disseminate Africa-focused safety reports to enhance informed regulation and decision-making in Africa.

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