SAHPRA
South African
Health Products
Regulatory Authority

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Communication to Stakeholders March 2022

MD035: USABILITY STUDIES FOR COVID 19 SELF TESTING KITS REQUIREMENTS

Background

On the 5th of March 2020, Minister of Health Zweli Mkhize confirmed the spread of the virus to South Africa, with the first known patient being a male citizen who tested positive upon his return from Italy. The vast range of self-testing kit as well as risk associated with the use of the self-testing kits requires that the South African population is taken into consideration. This will ensure that all aspects of safety, performance and quality of the self-test kits are adequately addressed through the guidelines.

The purpose of this document is to provide applicants with guidance on SAHPRA requirements concerning performance requirements (e.g. analytical and clinical sensitivity and specificity) and risk mitigation for COVID-19 rapid antigen self-tests.

This guidance refers to COVID-19 (caused by SARS-CoV-2) only and does not include self-tests to detect other types of coronavirus, or COVID-19 rapid antibody tests. COVID-19 rapid antigen self-tests are tests that allow individuals to collect a specimen, conduct a test and interpret the results by themselves. These tests can be performed in the home, without the involvement of a health professional. COVID-19 rapid antigen tests are most accurate when used in a symptomatic person within the first few days of showing symptoms (i.e. when the viral load is highest), although their accuracy has been shown to be lower than that of polymerase chain reaction (PCR) tests.

This document identifies key risks that must be mitigated and identifies conditions that may be imposed on the supply of self-test kits if they are to be approved by SAHPRA. Additional mitigation strategies, including conditions of inclusion may apply to individual devices on a case-by-case basis.

As self-tests will predominantly be used by lay persons, clinical evidence in the form of usability studies is required to establish performance of the test in the hands of these users. It is expected the clinical performance studies would include residual clinical patient samples in their usability studies.

The manufacturer is required to provide South Africa-specific usability studies, the study will reflect the performance of the test in a comparable setting and relevant to the South African population.

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SAHPRA also recommends the use standards such as *IEC 62366-1 Application of Usability Engineering to Medical Devices* to provide further guidance and considerations and how to document such usability studies

The following two phase approach for product performance evaluation is required:

1. Assay **analytical** performance evaluation as per specification criteria for COVID 19 Antigen test kits (Refer to MD033), which includes circulating VOC and **feasibility analysis** (qualitative assessment of kit components, biosafety and waste; test procedure and result interpretation using reference material and mock test results). A supplier should provide a minimum of 300 test cassettes and mock results (reactive [including weakly reactive], non-reactive and invalid).

2. A **usability** evaluation (age appropriate, language specific and education level end-users performed under health care worker observation) as detailed:

Inclusion criteria

1. study population should represent adults 18 years and older
2. Participants should represent varying education levels and ages and include individuals who may not use English as their preferred language.
3. Physical completion of all the steps required to complete the test, by at least 60 individuals will provide an indication of the reliability and robustness of the test. Ideally the invalid test rate would be expected to be ≤ 5% of the total tested (this includes defective tests or components).

Exclusion criteria

1. Participants with prior medical or laboratory training should be excluded.
2. Participants who have prior experience with self-collection or self-testing for COVID-19 should also be excluded

Minimum number of people to be included in the study:

Minimum of 100 lay users

Investigation environment:

The test to take place in an actual user environment or simulated environment with supervision but not intervention by the supervisor/observer

The entire workflow should be performed by each individual participant doing the test, including:

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sample collection and testing, followed by result interpretation (mock cassette with reactive, non-reactive and invalid result provided by supplier) without assistance, influence, or guidance from the study observers/ supervisors. The participant's test cassette will be discarded prior to test-time completion as results will not be used for patient management.

Observation Criteria

1. Ability of the user to interpret the Instruction for use, and to ensure the labelling is clear and easy to be followed
2. Derive questionnaire according to the following but not limited to:
   a. the ability of users to correctly comprehend instructions for use, limitations, diagrams, result interpretation and access to follow-up services.

The participants should be observed (either in person or by remote visual monitoring, such as a video conference) during sample collection and performance of the test and all difficulties noted down.

Interpretation of mock results:

Usability studies should also include the interpretation of mock test results under supervision:

1. To evaluate the ease of interpretation of results by a lay-user, mock test results should be read and interpreted by a minimum of 100 lay-users.
2. The mock test results should reflect a range of results including non-reactive, reactive (including weak reactive close to the cut-off or limit of detection of the test) and invalid.
3. Determination of concordance against reading and interpretation of the same mock test by professional or trained users for the test.

Mock test results will be randomised across enrolled participants based on the following for confirmation of sensitivity and specificity:

- Diagnostic sensitivity, non-supervised – at least 30 lay users will be provided with a mock reactive test result. These will comprise 5 reactive and 25 weakly reactive test result
- Diagnostic specificity, non-supervised – at least 55 lay users will be provided with a mock non-reactive test result.
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- Invalid rate (non-supervised) will be determined from 5 lay-users provided with an invalid mock test result.

1. Demonstration of the benefit of a test and effectiveness of risk mitigation measures in the self-testing environment may further be supported by a documented review of relevant published literature.
2. Applicant must mitigate any risks and demonstrate overall benefits of the self-test kits outweighs any residual risks associated with its use.

3. If the test uses an app to analyse or assist in the interpretation of results this needs to be used in the study to demonstrate there is no negative impact on interpretation, particularly for weak positive results.
4. A significant inter-reader variability (e.g. ≥ 5%) for clearly positive or negative results implies the following on the test kit:

   It is not easy to use, the IFU is not clear enough, or the test may be difficult to interpret resulting in an increased rate of false negative or false positive results.

Invalid test rate

1. The incidence of operational errors and test system failures (e.g. failure to sample correctly or complete each of the sequential steps required to perform the test, resulting in an invalid or unreadable result), or where the user is unable to interpret the result leading to an invalid result, should be determined