

MD036: COVID 19 TEST KITS BATCH VERIFICATION

BACKGROUND

1. The COVID-19 pandemic is caused by SARS-CoV-2, a novel coronavirus that originated in Wuhan, China in late 2019. The virus has since spread around the world, with novel variants of concern causing new waves of infection.
 - i. Testing is a critical component of COVID-19 control and prevention strategies. Testing for SARS-CoV-2 infection using diagnostic tests is an approach that can be used to broaden access to COVID-19 testing, alongside conventional testing methods.
 - ii. Diagnostic tests are designed to directly detect SARS-CoV-2 proteins produced by replicating virus in respiratory secretions and have been developed as both laboratory-based tests, and for near-patient use, so-called rapid diagnostic tests, or RDTs.
 - iii. COVID-19 rapid antigen provides a presumptive test result for the SARS-CoV-2 virus and is intended to be used by health care professionals, in the home or similar environment by a lay person.
 - iv. SAHPRA has taken the position to authorise the COVID-19 tests that meet the target product profile under Section 21 authorisation. SAHPRA has adopted the specification criteria from stringent regulatory authorities for SARS-CoV-2 diagnostic tests.

CURRENT REQUIREMENT

2. In terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965 as amended), the Authority may authorise the sale of unregistered medicines, medical devices or IVDs for certain purposes—
 - i. The Authority may in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or IVD which is not registered.
 - ii. Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.
 - iii. The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).

3. As per the Medicines and Related Substances Act, 1965 (Act 101 of 1965 as amended), the person authorised to sell a medical device according to Section 21 is responsible for post-market surveillance and adverse event reporting in line with Regulation 17 (Adverse event reporting and vigilance for medical devices or IVDs) of the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 09 December 2016.
4. Where a Section 21 approval has been issued for a medical device, reports on the product performance, use, post-market surveillance and adverse events must be submitted to SAHPRA on a monthly basis for all lots or batches supplied to South Africa.
5. Review of the requirements for lot/ batch testing of COVID 19 test kits has taken place with the National reference laboratory and NICD.

REVISED REQUIREMENT

6. SAHPRA , NICD and NHLS have taken the decision to amend the requirements relating to testing of COVID 19 test kits.
7. Monthly lot/batch testing of COVID 19 test kits is no longer required with effect from 15 July 2022.

NOTE:

8. The Authority reserves the right to request any additional information such as lot/batch testing when necessary to establish the safety, quality and performance of an IVD in keeping with the knowledge current at the time of evaluation.

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