



MEDIA RELEASE

SAHPRA approves antigen self-test kits for public use

Embargo: Immediate release

Pretoria, 24 November 2022 – In the past year, the South African Health Products Regulatory Authority (SAHPRA) approved the antigen test kits for use by healthcare professionals.

SAHPRA has now approved seven (7) COVID-19 antigen self-test kits that can be used as self-test/ at home tests by individuals as per the Instruction for Use (IFU) of the product. Information on storage and disposal of antigen self-test kits may be found on the product's IFU. The public is urged to comply with proper use and disposal of the tests as per the IFU.

This SAHPRA authorisation allows organisations that received approval to market and sell the self-test kits to the public. These test kits can be accessed at any pharmacy. For the detailed list of approved self-test kits, please visit this link: <https://www.sahpra.org.za/medical-devices/medical-devices-and-in-vitro-diagnostics-test-kits/>.

Using antigen self-test kits

When using the COVID-19 antigen self-test kit/s, the results will either be positive or negative. What does this mean? If one gets a positive result, it is necessary to get a Real-Time Polymerase Chain Reaction (RT-PCR) test as a confirmatory test. It is also important to note that a negative result does not mean that the person does not have SARS COVID-19. If a person has or shows symptoms of SARS COVID-19, they should have a RT-PCR test done and follow medical advice accordingly.

“These test kits offer a quick and viable alternative for COVID-19 screening. Performance testing was done in collaboration with our National Reference Laboratory (i.e., the National Health Laboratory Services – NHLS) to ensure that quality test kits are available to the public. SAHPRA always ensures public safety when approving any health product,” indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

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About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.

Notes to Editors:

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A podcast will be recorded and posted on the home page. Scroll down the home page to “**SAHPRA TV and Podcasts**”. Podcasts appear on the right-hand side.

Should you request an interview for television, please send your request to media@sahpra.org.za and copy yuveng@sahpra.org.za. Include your discussion points in your request.