

By SUTHEHIRA GOVENDER

● While Covid self-test kits have long been available in the UK, US and Europe, South Africa has just caught up after the recent approval of a version devised by a Cape Town biotechnologist.

Ashley Uys, head of Medical Diagnostech, recently got the green light from the South African Health Products Regulatory Authority (Sahpra) for the first locally made antigen rapid test kit.

The home-test kit will work in tandem with a mobile app, HealthPulse TestNow, designed to assist in conducting the test, interpreting the result, and reporting it directly to the national database.

The app, designed by a US-based company, Audere, has been validated by the National Health Laboratory Services to ensure the test can be conducted at home.

The test, which has been 18 months in the making, will be on shelves by the end of April and will cost around R50.

Uys says despite the pandemic being in a lull, tests are still important to help keep Covid-19 under control.

He said Medical Diagnostech has also developed a test kit to distinguish between flu and Covid-19.

"This is currently undergoing evaluations for regulatory approval. We anticipate this to be ready from October 2023. We also intend on availing a version for cold/flu/Covid-19. This is currently in development."

Uys said Covid-19 "is still infecting people".

Better late than never, SA Covid self-test is here



Above, Ashley Uys, head of Medical Diagnostech, whose Covid-19 self-testing kit will soon hit the shelves. Left, the self-test kits. Pictures: Supplied



According to the latest epidemiological report by the National Institute for Communicable Diseases – based on data collected up to March 25 – more than 4 million laboratory-confirmed Covid-19 cases had been detected in South Africa.

Of these, 2,099 cases were reported two weeks ago.

"Travel restrictions in some countries will continue to apply for Covid-19 for a while to come," Uys said.

"Hence, test kits will be required. Winter is coming as well, and we usually see a spike in infections. It still affects the old and ageing, with new strains appearing."

He attributed the delay in approving the test to the regulatory process of getting both the test and app approved by authorities.

"Usually rapid diagnostic tests (RDT) are required to undergo analytical validation by the National Health Laboratory Service (NHLS) as part of the regulatory submission."

"Because our test kit comes with a companion app, the regulatory process... was expanded by Sahpra and the NHLS... They had to draft a new protocol to validate the app as well."

"This means the app was subjected to a multi-provincial study to determine whether the lay person can successfully use the RDT along with the app. This process took quite some time as this was the first of its kind in South Africa," said Uys.

The South African Medical Research Council said in a statement self-testing was an important component of public health strategies worldwide.

"However, challenges exist with accurate and reliable test administration, interpretation and collection of data that can com-



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Prof Salm Abdool Karim, infectious diseases epidemiologist

promise the benefits of these efforts.

"HealthPulse TestNow is designed to improve an individual's self-testing aptitude while seamlessly connecting ministries of health with test data in an effort to maximise the end-to-end impact of public health programmes."

Infectious diseases epidemiologist professor Salm Abdool Karim said: "If we take the lessons that we learnt from HIV, having a simple, rapid test that you can administer yourself is an important part of the tools that will help us best control these diseases."

"One of the essential elements in tackling Covid going forward is that we want to reduce the exposure in elderly people. Elderly people still get more severe disease than younger people even if they are vaccinated."

"Now if you want to have a test you have to go to a doctor or to a laboratory to have a swab taken."

Abdool Karim believes this could discourage testing.

"It becomes important, particularly for those who interact with older people, to have access to these rapid tests."

He said the approval took too long.

"Eighteen months ago the tests were available everywhere in the world except here. We just took too long."