SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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Communication to Stakeholders March 2022

MD034: Conditions for use of COVID-19 antigen self-test kits

BACKGROUND

The primary goal of self-testing is to aid with the early detection of SARS-CoV-2, to reduce transmission, and enable people to follow public health measures to control COVID-19 and keep societies open during the pandemic. Ag-RDT self-tests play an important role as they can enable decentralised testing and thereby increase access to testing. Self-testing using Ag-RDTs can provide real-time information and empower individuals to know their COVID-19 status and take individual-level actions accordingly. Self-testing for both symptomatic and asymptomatic, vaccinated and unvaccinated individuals can be an efficient way to limit the spread of the disease. It is important that self-testing is offered as an additional testing option, and not replace existing COVID-19 testing services.

SAHPRA has taken the position to authorise the COVID-19 antigen self-tests kits that meet the target product profile (MD33 -) under Section 21 authorisation. The Australian Therapeutic Goods Administration, specification criteria for COVID-19 rapid antigen self-tests refer to MD033.

1. In terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the Authority may authorise the sale of unregistered medicines, medical devices or IVDs for certain purposes—

   a) *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.*

   b) *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.*

   c) *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).*

2. **Understanding antigen testing results**

   The testing is also not to be used to diagnose infection.

   - Antigen testing detects the presence of antigens, **not** the presence of the SARS-CoV-2 virus.
   - A positive self-test result means that the test detected SARS-CoV-2, and that the individual is very likely to COVID-19 positive. Individuals with a positive test should follow national public health guidance around isolation to reduce the risk of spreading disease to others. Reference is made to National Coronavirus Regulations and will be updated accordingly. Current regulation as at 15 February 2022 can be found here: https://sacoronavirus.co.za/2022/02/03/summary-of-level-1-regulations-as-of-01-february-2022/
   - A negative self-test result means that the test did not detect the virus but it does not rule out infection. Repeating the test within a few days, with at least 24 hours between tests, will increase the confidence that the individual is not infected.

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- A self-test result should not be used for certification purposes

USE OF COVID-19 Antigen TEST KITS

3. **SARS-CoV-2 self-testing can be done in two ways:**

- Directly assisted SARS-CoV-2 self-testing, where a trained health worker provides in-person support on how to use the kit and how to interpret results.
- Unassisted SARS-CoV-2 self-testing, where the end-user performs the test using the information package in the kit itself, without any in person assistance by a health worker.

As with all self-testing, users must be provided with access to additional support such as telephone hotlines, brochures or instructional videos. These should all have received pre-approval from the manufacturer and reviewed for ease prior to implementation .Self-test results should be used and interpreted according to the national algorithm, and should not replace professional use rapid diagnostic tests or PCR testing where such testing is appropriate and available

Testing for specific COVID-19 antigens is recommended for the following purposes:

- To identify recent or remote past SARS-CoV-2 infections
- Targeted cohort surveillance
- Households and workplaces
- Schools
- Community screening, specifically for serosurveys or hot spot tracing
- Population-level epidemiologic studies and surveillance programmes
- As part of scientific research studies

4. **Limitations of SARS-CoV-2 antigen testing:**

- Results from COVID-19 antigen test kits should not be used as the basis to clinically diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains.

5. Point-of-care (POC) COVID-19 antigen self-test kits such as nasopharyngeal swab , Throat swab, oral Fluid or Saliva are for **lay persons**

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AUTHORISATION FOR USE OF UNREGISTERED COVID-19 ANTIGEN SELF-TEST KITS

6. Authorisation for the sale of an unregistered in-vitro diagnostic (IVD), in terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), for COVID-19 rapid antigen self-tests , will be issued by SAHPRA provided that the COVID-19 rapid antigen self-tests meets the performance criteria as stated in MD033

7. Only SAHPRA licence holders who are authorised to manufacture and/or distribute COVID-19 rapid antigen self-tests listed /s are eligible to receive Section 21 authorisation. **Any other applications for Section 21 authorisation for the COVID-19 antigen test kit/s will not be accepted.**

8. Only COVID-19 rapid antigen self-tests that have been authorised by SAHPRA may be used.

9. COVID-19 rapid antigen self-tests may only be supplied by valid SAHPRA licence holders.

10. The name of the COVID-19 rapid antigen self-tests that has been authorised by SAHPRA will be listed on the SAHPRA licence.

11. The list of authorised COVID-19 rapid antigen self-tests and corresponding SAHPRA licence holders is published on the SAHPRA website (www.sahpra.org.za).

12. The SAHPRA licence holder 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. Reports on product performance, use, post-market surveillance and adverse events must be submitted to SAHPRA on a monthly basis for all lots supplied to South Africa.

13. The use of COVID-19 rapid antigen self-tests beyond the scope of the national testing algorithm is prohibited and must be reported to SAHPRA.

14. **The use and/or sale of COVID-19 rapid antigen self-tests that have not been authorised by SAHPRA is prohibited and must be reported to SAHPRA.**

15. The sale of a COVID-19 rapid antigen self-tests by an individual and/or company that is not licensed by SAHPRA and/or is not authorised by SAHPRA to sell the specific is prohibited and must be reported to SAHPRA.

16. Regulation 21(1) (a) of the Regulations Relating to Medical Devices and In vitro Diagnostics be followed, A Class C and Class D medical device/IVD may be advertised to Healthcare professionals only

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March 2022