

MD016: Conditions for use of COVID-19 serological test kits

BACKGROUND

It is important to note that COVID-19 serological tests do not detect the virus itself. Instead, they detect the antibodies produced in response to an infection. Serological tests are not appropriate for clinical diagnosis of COVID-19. This is largely because of variability in the time required after infection to develop antibodies.

SAHPRA has however taken the position (MD005) to authorise the COVID-19 serology tests that meet the target product profile (MD007) under Section 21 authorisation.

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 serological testing results**

Serological testing detects the presence of antibodies, **not** the presence of the SARS-CoV-2 virus. This testing is also not to be used to diagnose infection. The immune response to a virus involves the creation of different types of antibodies produced at different stages of an infection:

- Early antibodies, called IgM antibodies, provide the first indication of the body's response to an infection. These antibodies are not as specific and generally are not as long lasting, so interpreting their significance requires clinical experience.
- IgG antibodies are specific to a virus, such as the SARS-CoV-2 virus. Early research results suggest these antibodies can be reliably detected 14 days after a person is infected with COVID-19.

The relationship between antibodies and immunity to infection with SARS-CoV-2 is still unknown. It is unclear whether people with antibodies are immune to re-infection or if they are still infectious to others.

Also, antibodies are present for an undetermined period of time after an infection has ended. For the above reasons, serological test results should be interpreted with caution.

USE OF COVID-19 SEROLOGICAL TEST KITS

3. The use of COVID-19 serological test kit/s authorised under Section 21 will be limited for use under the **national testing protocol only**.

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

- To supplement nucleic acid (e.g. PCR) testing for the diagnosis of suspected COVID-19
- To identify recent or remote past SARS-CoV-2 infections
- Targeted cohort surveillance
- Community screening, specifically for serosurveys or hot spot tracing
- Population-level epidemiologic studies and surveillance programmes
- Identification of convalescent plasma donors
- As part of scientific research studies

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

- Results from COVID-19 serological 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.
- Follow-up testing with a molecular diagnostic must be performed to rule out infection in these individuals.

5. Point-of-care (POC) COVID-19 serological test kits such as finger-prick test / rapid test kits are for professional use only and must be used under the direct supervision of a healthcare professional only.

6. Laboratory-based COVID-19 serological test kits such as enzyme-linked immunosorbent assays (ELISA) may only be used by laboratories accredited to ISO 15189:2012 for medical laboratories and the test results must be reviewed by a pathologist.

AUTHORISATION FOR USE OF UNREGISTERED COVID-19 SEROLOGICAL TEST KITS

7. 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 serological test kit/s, will be issued by SAHPRA provided that the COVID-19 serological test kit/s meets the performance criteria (Refer to MD007).

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

9. Only COVID-19 serological test kit/s that have been authorised by SAHPRA may be used. COVID-19 serological test kit/s may only be supplied by valid SAHPRA licence holders. The name of the COVID-19 serological test kit/s that has been authorised by SAHPRA will be listed on the SAHPRA licence. The list of authorised COVID-19 serological test kit/s and corresponding SAHPRA licence holders is published on the SAHPRA website (www.sahpra.org.za).

10. As Covid-19 is a notifiable disease, each test that is used for testing must be accurately recorded and reported to the National Health Laboratory Service (NHLS) through the approved platform defined by the NHLS.

11. 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.

12. The use of COVID-19 serological test kit/s beyond the scope of the national testing algorithm is prohibited and must be reported to SAHPRA.
13. **The use and/or sale of COVID-19 serological test kit/s that have not been authorised by SAHPRA is prohibited and must be reported to SAHPRA.**
14. The sale of a COVID-19 serological test kit/s by an individual and/or company that is not licensed by SAHPRA and/or is not authorised by SAHPRA to sell the specific COVID-19 serological test kit/s is prohibited and must be reported to SAHPRA.

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