MEDIA RELEASE

SAHPRA Approves SARS-Cov-2 serology Test Kits

Embargo: Immediate release

Pretoria, 25 August 2020 – SAHPRA has issued Section 21 authorisation for one serological test kit (rapid, point of care test kit) and five lab-based SARS-Cov-2 serology tests.

For the rapid, point of care serology tests, the manufacturer is Zhejiang Orient Gene Biotech. There are seven licence holders for this test kit that have been authorised to date:

- Direct Retail Goods (Pty) Ltd
- Doctor Four You Practice Managers (Pty) Ltd
- Inqaba Health Solutions (Pty) Ltd
- Link Medical Solutions (Pty) Ltd
- Sinosa Trading (Pty) Ltd
- Tip Top Trade (Pty) Ltd
- Nu-World Industries (Pty) Ltd

Three manufacturers of lab-based serology tests that have been granted Section 21 authorisation to date are:

- Roche Diagnostics (Pty) Ltd
- Abbott Laboratories South Africa (Pty) Ltd
- Euroimmun Medical Laboratory Diagnostics South Africa (Pty) Ltd

The difference between the molecular PCR test and the serology tests is that the PCR tests are able to detect and diagnose whether one has been infected with COVID-19 and thus give a clinical diagnosis. Whilst the latter, i.e. serology tests, can detect if one has developed antibodies for COVID-19 or not. Serology tests cannot be used for clinical diagnosis.

Serology tests cannot be conducted at home, they have to be administered by qualified health care professionals and must have been validated. These tests should only be used within the National Department of Health's surveillance strategy. Licence holders are required to report any product quality problems identified with their products in accordance with Regulation 40 of the Medicines and related substances Act, 1965 (Act 101 of 1965).

"Rapid test kits cannot be used to clinically diagnose COVID-19 cases, but they may play a role in research, epidemiological as well as sero-surveillance studies. Rapid test kits are not recommended by WHO for clinical diagnosis of SARS-Cov-2 infection," indicates Dr Boitumelo Semete-Makokotlela, CEO of SAHPRA.

The list of licenced medical device establishments authorised to manufacture or distribute tests has been published on the SAHPRA website. (http://www.sahpra.org.za/be-prepared-for-covid-19/)

The regulatory requirements for rapid test kits were determined based on the existing regulatory framework for medical devices and IVDs that was implemented in 2016 and that is in line with the World Health Organization Global Model Regulatory Framework for Medical Devices including In-vitro Diagnostics and the guidance developed by the International Medical Device Regulatory Forum (IMDRF). The regulatory requirements for serological test kits (MD002: Regulatory Requirements for the manufacture, distribution or wholesale of Serological COVID-19 Rapid Test Kits) were published on the 30 March 2020 on the SAHPRA website and the specification criteria for serological test kits had been developed (MD007) and published on the 20 April 2020.

Since these tests may present with lower sensitivities, it is recommended that PCR testing remains the modality for acute clinical diagnosis of COVID-19. The use case for these tests is thus limited to specific use cases as per the MD021 guideline published on the SAHPRA website (https://www.sahpra.org.za/medical-devices/)

Rapid test kits may only be manufactured or imported by SAHPRA licensed medical device establishments once the test kits have been validated by an independent laboratory. SAHPRA licence holders are responsible for ensuring compliance with the Medicines and Related Substances Act, 1965 (Act 101 of 1965) which sets out the requirements for ensuring the safety, quality and performance of medical devices and IVDs. Licence holders are required to have in place the necessary vigilance strategies for monitoring the performance of their health products.

SARS CoV-2 test kits cannot be sold to the public. SARS CoV-2 test kits are class D medical devices and in terms of Regulation 21 (1)(a) may not be advertised to the public. Any use of unauthorised test kits or advertisements must be reported to SAHPRA's Regulatory Compliance unit. Contact Mokgadi.fafudi@sahpra.org.za.

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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.