MEDIA RELEASE

COVID-19 – The Appropriate place for Rapid Test Kits

Embargo: Immediate release

Pretoria, 30 March 2020 - In line with the recommendation of the South African National Institute for Communicable Disease (NICD) and the recommendation of the World Health Organization (WHO), SAHPRA wishes to point out that the so-called **Rapid test kits (serological test kits)** that are being offered for the diagnosis of COVID-19 are not suitable for this purpose. They are not helpful to guide decision-making regarding patient management, decisions around the need for quarantine, isolation or contact tracing. Serological tests are used for epidemiological surveys, but not for the diagnosis of acute infections.

CLARITY ON COVID-19

COVID-19 is the disease caused when a person is infected by the novel coronavirus called SARS-CoV-2. A test can be performed to determine if a person has been infected with the **SARS-CoV-2** virus and has the **COVID-19** disease. There are **two** types of tests that can be used:

1) Molecular (or PCR test): Tests that detect the presence of the actual SARS-CoV-2 virus in your body by detecting the genetic material of the actual virus (molecular tests). This test is done by taking a swab from your mouth or nose. This test is complicated and needs to be done in a laboratory. These tests can detect the virus even before a patient becomes unwell.
2) Serological tests (or Rapid Test) Tests that detect whether your body has produced antibodies to the SARS-CoV-2 infection (serological tests). This is done through a finger-prick blood test It takes many days for the body to develop antibodies against the virus so people can already

have the SARS-CoV-2 virus and can be spreading the infection to other people but we would not be able to detect their antibodies.

RAPID TEST KITS

Since the beginning of the COVID-19 pandemic, a number of manufacturers have developed tests that are referred to as Serological, Rapid or Point of Care (PoC) tests. They are sometimes referred to as IgG or IgM tests. These rapid and PoC tests (serological) are not intended for **diagnosis of acute infections** and should not be relied upon for self-testing as they may be interpreted as meaning that someone is not infected with the virus when they may actually be infected already. These tests are designed to be used under the direct supervision of a **health care professional** in epidemiological surveys.

"It is vital that all COVID-19 tests should be conducted by a health care professional and processed by a certified laboratory to ensure accuracy of decision-making, treatment and advice. The health care professional can also decide on whether to alert the relevant health authorities and conduct contact tracing. This will ensure that authorities can trace infections and take action to stop further spread of the infection. The South African public is reminded that at this stage, the use of serological test kits is not recommended. The public is discouraged from using rapid test kits (serological), claiming that you can test yourself at home or test yourself under the supervision of health care professional to determine whether or not you have a COVID-19 infection. Furthermore, all tests and establishments manufacturing or distributing such tests should be licensed by SAHPRA," indicates **SAHPRA CEO**, Dr Boitumelo Semete-Makokotlela.

SAHPRA has implemented an expedited licence process for new applications and amendments to current licences in order to support the supply of medical devices that may be required in response to the COVID-19 pandemic.

SAHPRA appeals to the public to report to SAHPRA any company/individual/website selling COVID-19 Rapid test kits so that SAHPRA can take the necessary action in this regard. Please provide the details to the Law Enforcement Unit (Contact information listed below).

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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.