



MEDIA RELEASE

SAHPRA Approves First WHO EUL Mpox Test Kit

Embargo: Immediate release

Pretoria, 22 May 2025 – The South African Health Products Regulatory Authority (SAHPRA) having applied Reliance on the World Health Organization (WHO) PQ assessment under Emergency Use Listing, has listed the first mpox (monkeypox) *in vitro* diagnostic (IVD). This serves as an important step in improving global access to mpox testing by using a reliance process.

The emergency use approval of the Alinity m MPX assay, developed by Abbott Molecular Inc. and licensed to Abbott Laboratories South Africa (Pty) Ltd, represents a critical advancement in expanding diagnostic capacity amid mpox outbreaks. Rapid and accurate testing is essential for early detection, timely treatment, and effective containment of the virus.

“For SAHPRA to have been able to list this assay timeously, post a WHO PQ EUL, this marks a significant milestone in aiding global access to mpox testing by leveraging regulatory reliance mechanisms,” says Dr Boitumelo Semete-Makokotlela, SAHPRA’s Chief Executive Officer.

The regulatory requirements for mpox diagnostics can be found in a communication to industry: Issue No.: [MD01-2024/25 v1](#) and further WHO mpox diagnostics which was guided by:

<https://www.sahpra.org.za/wp-content/uploads/2024/09/SAHPRA-Communication-to-External-Stakeholders-Mpox-Diagnostic-Tests.pdf>

Currently, only molecular RT-PCR (reverse transcription polymerase chain reaction) tests are considered for approval by SAHPRA. These RT-PCR tests are nasal swab tests. African Centres for Diseases (Africa CDC) and WHO have noted that there is no independently

validated antigen RDT (Rapid Diagnostic Tests) in the market that demonstrated the minimum clinical sensitivity of 80% that is suitable for mpox testing in Africa. Therefore, mpox antigen and antibody rapid tests kits (including self-test kits) are not recommended for use.

Ends

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Notes to Editors:

SAHPRA will post this media release on its website. Navigate to the News section on the website.

Should you wish to request an interview, please send your request to media@sahpra.org.za and yuveng@sahpra.org.za

Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - <https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/>

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, 101 of 1965, as amended, as well as the Hazardous Substances Act, 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.