

COMMUNICATION TO STAKEHOLDERS

Issue No.: MD02-2024/2025

9 April 2025

MPOX DIAGNOSTIC TESTS

This communication is intended to provide an update to industry stakeholders concerning Mpox (formerly monkeypox) diagnostic tests in South Africa.

In line with Africa Centres for Disease Control and Prevention (Africa CDC) declaring Mpox a Public Health Emergency of Continental Security (PHECS) in Africa on 13 August 2024, diagnostic tests are critical for the implementation of a control and prevention strategy against infectious disease spread. Therefore, the South African Health Products Regulatory Authority (SAHPRA) is mandated to ensure the availability of Mpox diagnostics that comply with acceptable levels of safety, quality and performance.

This communication serves to inform industry stakeholders that all Mpox diagnostic tests that are to be distributed and used in South Africa require verification and approval by SAHPRA under the medical device establishment licence issued in terms of Section 22C of the Medicines and Related Substances Act, 101 of 1965, as amended. **No Mpox diagnostic tests will be allowed to be distributed and/or used in South Africa without prior approval by SAHPRA.**

Medical device establishment licence holders who have already listed Mpox diagnostic tests prior to the publication of this communication will be further engaged by SAHPRA regarding the verification and approval status of their products.

Only molecular Reverse Transcription-Polymerase Chain Reaction (RT-PCR) tests are currently considered for approval by SAHPRA. Africa CDC¹ and WHO² have noted that there is no independently validated antigen Rapid Diagnostic Test (RDT) 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 test kits (including self-test kits) are not recommended for use.

The regulatory requirements for Mpox diagnostics can be found in Communication to Industry: Issue No.: MD01-2024/25 v1

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¹ Africa CDC Mpox <https://africacdc.org/news-item/africa-cdc-declares-mpox-a-public-health-emergency-of-continental-security-mobilizing-resources-across-the-continent/>

² WHO/MPX/Laboratory/2024.1 <https://www.who.int/news/item/29-08-2024-who-urges-rapid-access-to-mpox-diagnostic-tests--invites-manufacturers-to-emergency-review>