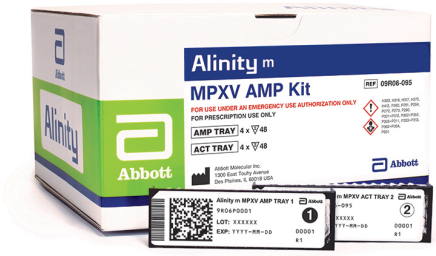
BioSpectrum
the business of Bio & Health Sciences

WHO approves first mpox diagnostic test by Abbott for emergency use

04 October 2024 | News

Alinity m MPXV assay is a real-time PCR test that enables detection of monkeypox virus (clade I/II) DNA from human skin lesion swabs



The World Health Organisation (WHO) has listed the first mpox in vitro diagnostic (IVD) under its Emergency Use Listing (EUL) procedure, an important step in improving global access to mpox testing.

The approval for emergency use of the Alinity m MPXV assay, manufactured by Abbott Molecular Inc., will be pivotal in expanding diagnostic capacity in countries facing mpox outbreaks, where the need for quick and accurate testing has risen sharply. Early diagnosis of mpox enables timely treatment and care, and control of the virus.

Limited testing capacity and delays in confirming mpox cases persist in Africa, contributing to the continued spread of the virus. In 2024, over 30, 000 suspected cases have been reported across the region, with the highest numbers in the Democratic Republic of the Congo, Burundi, and Nigeria. In the Democratic Republic of the Congo, only 37% of suspected cases have been tested this year.

The presence of the monkeypox virus is confirmed by nucleic acid amplification testing (NAAT), such as real-time or conventional polymerase chain reaction (PCR), as stated in the WHO Interim Guidance on Diagnostic testing for the monkeypox virus (MPXV). And the recommended specimen type for diagnostic confirmation of monkeypox virus (MPXV) infection in suspected cases is lesion material.

The Alinity m MPXV assay is a real-time PCR test that enables detection of monkeypox virus (clade I/II) DNA from human skin lesion swabs. It is specifically designed for use by trained clinical laboratory personnel who are proficient in PCR techniques and IVD procedures. By detecting DNA from pustular or vesicular rash samples, laboratory and health workers can confirm suspected mpox cases efficiently and effectively.