MEDIA ADVISORY
Monkeypox declared public health emergency: diagnostics and disease surveillance current status

- **On 23 July 2022, the World Health Organization declared monkeypox a public health emergency of international concern**
- **FIND continues to track the pipeline of diagnostic tests for monkeypox: to date, it includes 93 tests, 55 of which have been CE-IVD marked in Europe and one US FDA approved**
- **Data continue to indicate that most cases are not life-threatening, and the disease is not easily passed from person to person**

GENEVA, SWITZERLAND – 25 July 2022. On Saturday, 23 July 2022, the World Health Organization (WHO) declared the ongoing outbreak of monkeypox to be a public health emergency of international concern (PHEIC). The declaration came after the International Health Regulations (IHR) Emergency Committee was convened by WHO to assess the multi-country monkeypox outbreak and provide recommendations. The final decision to declare a PHEIC rests with WHO Director General, Dr Tedros Adhanom Ghebreyesus.

This highest alert level by WHO is intended to draw global attention and resources to stem the spread of the disease, and as a call to countries to prioritize their outbreak response. It has been prompted by significant concerns about the way the disease is spreading globally, especially in Europe and North America, and among people with no links to travel to Africa, where monkeypox is endemic, carried by rodents and other wild animals.

The monkeypox virus that is currently spreading in the Global North belongs to the less deadly West Africa clade. A second clade generally found in the Congo Basin of Central Africa has a case fatality of up to 10%, but has not been noted during this outbreak outside of Africa. The PHEIC announcement is a call to action to boost diagnostic testing and surveillance systems in all countries of the world so that cases of monkeypox can be swiftly identified and counter-measures taken, including provision of patient care and tracing and vaccination of contacts – which can result in stemming transmission. The IHR Emergency Committee also noted that efforts must be redoubled to address the disease in endemic areas of Africa.

Dr Daniel Bausch, Senior Director of Emerging Threats & Global Health Security at FIND, is a Member of the WHO IHR Emergency Committee. Dr Bausch said: “There is no doubt that the number of monkeypox cases continues to grow in some areas of the Global North, although the worldwide risk remains moderate. Regardless of whether a PHEIC is declared (a nuanced designation for which some revision of the process is required, as Dr Tedros mentioned in his statement), the situation requires a global effort to address the emergency, starting with enhanced surveillance and testing, and not forgetting the Global South, where monkeypox is not a new disease”.

FIND has been tracking the monkeypox testing landscape since the start of this year's outbreak. Our database currently includes 93 tests:

- 79 molecular tests (including 6 cartridge-based), of which 49 have been CE-IVD marked in Europe, and one that has been approved by the US FDA
- 11 rapid diagnostic tests, 7 for antigen detection (5 CE-IVD marked) and 4 for antibody (1 CE-IVD marked)
- 3 ELISA or other serologic tests (0 CE-IVD marked)

FIND is presently working with a host of partners to validate some of these tests.

Laboratory confirmation of monkeypox infection relies principally on nucleic acid amplification tests, such as PCR, performed on material from the skin lesion. Testing of other body fluids and tissues, including oropharyngeal swabs, urine, semen, rectal and/or genital swabs, may be indicated based on the clinical presentation and location of the lesions. WHO issued interim guidance for laboratory testing for the monkeypox virus on 23 May 2022.

The monkeypox emergence has highlighted challenges faced by diagnostic developers that may have been hidden by the fast pace of innovation at the start of the COVID-19 pandemic. Test manufacturers have always struggled to respond to sporadic and unpredictable demand for outbreak diseases such as monkeypox. Ensuring that tests can be developed, made available and implemented quickly requires access to well-characterized disease samples and the circulating pathogen, clinical trial networks that can be activated to validate new tests and provide data for regulatory review, production lines standing ready, import and export systems being in place, and health workers being trained and ready to use the tests. All of these elements require investment, with little return on the horizon in the vast majority of cases. FIND's efforts on the 100 Days Mission to respond to future pandemic threats seeks to address these challenges.

The uncharacteristic spread of monkeypox underlines the need for sustained global surveillance systems that can detect emerging viruses in every country in the world. The focus on diagnostics for COVID-19 has boosted testing and surveillance capacity worldwide that can be useful for monkeypox, but dramatic inequities remain in low- and middle-income countries.

Developers are invited to submit details of their tests for inclusion in our database. In case of queries about the submission process, please contact testdirectory@finddx.org.

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About FIND

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. We connect countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis, and save US$1 billion in healthcare costs to patients and health systems. We are co-convener of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, and a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. For more information, please visit www.finddx.org

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