UPDATED MEDIA ADVISORY
Monkeypox: diagnostics and disease surveillance current status

- **FIND is tracking the pipeline of diagnostic tests for monkeypox. Developers are invited to submit details of their tests for inclusion in this database**
- **FIND will be presenting an overview of available diagnostics and those in the pipeline, as well as discussing laboratory research needs, at the upcoming WHO R&D Blueprint meeting *Monkeypox research: What are the knowledge gaps and priority research questions?* on 2 June 2022, 13:00–19:30 CEST**
- **Data so far indicate that most cases are not life-threatening, and the disease is not easily passed from person to person. In contrast to SARS-CoV-2, monkeypox is a DNA virus; these are usually more stable with regard to mutations and evolution of new variants**
- **Diagnostic capacity for testing and surveillance that was ramped up for COVID-19 will be helpful, but the current situation underscores the need for global surveillance for emerging pathogens and the challenges of boosting capacity to contain outbreaks when and where needed**

GENEVA, SWITZERLAND – updated 25 May 2022 (originally published 24 May 2022). Diagnostic testing and disease surveillance are back in the spotlight as scientists and public health workers closely monitor the current outbreak of monkeypox that has emerged in cities across Europe, the US, Australia and Canada. While the disease is not easily contracted, and in most cases is not life-threatening, the epidemiology of this outbreak is different to that which has been seen previously. Lack of routine vaccination for smallpox after eradication of that disease in 1980 may have contributed to an increase in monkeypox cases in humans in recent decades.

Monkeypox virus was first discovered in 1958 and is known to be endemic in 12 countries in Africa, four of which have reported cases to the World Health Organization (WHO) in the period 15 December 2021 to 1 May 2022. There are two groups or "clades", one found in the Congo Basin of Central Africa with a case fatality of up to 10%, and one in West Africa, with a case fatality of around 3%. Preliminary genomic sequence data from a patient in Portugal in the present outbreak showed the virus to belong to the less dangerous West African clade. In contrast to SARS-CoV-2, monkeypox is a DNA virus, a type of virus which is usually more stable with regard to mutations and evolution of new variants. There is no evidence to date that the monkeypox virus in this outbreak has fundamentally changed its composition relative to previously known viruses.

In the early clinical stages, monkeypox can appear similar to more common rash-causing diseases, such as chickenpox, but it can usually be differentiated because the monkeypox rash often extends to the palms of the hands and soles of the feet, which are spared in most other diseases. However, clinical presentations and severity may vary, and atypical presentations have been noted during this outbreak.

On 23 May 2022, WHO issued interim guidance for laboratory testing for the monkeypox virus. Laboratory confirmation of monkeypox 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. However, data on the accuracy of testing on these samples is still limited.

Until this outbreak in high-income countries, there were no commercially available PCR tests for the virus. However, a number of primer and probe sequence sets for PCR assays for monkeypox virus have been published and these have been used for in-house assays in laboratories with appropriate capacities. Dedicated monkeypox tests that can run on existing systems, including the GeneXpert platform, have been developed but are not yet commercially available.

A number of commercial tests are now coming online, and FIND is tracking the pipeline of diagnostic tests for monkeypox. Developers are invited to submit details of their tests for inclusion in this database. In case of queries about the submission process, please contact testdirectory@finddx.org.

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 relies on access to well-characterized disease samples that can be used to validate new tests, clinical trial networks that can be activated to 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.

While monkeypox is not easily transmissible and the present outbreak gives no cause for panic, its emergence 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.

Daniel Bausch, Director of Emerging Threats and Global Health Security at FIND, will present an overview of available diagnostics and those in the pipeline as well as discussing laboratory research needs at the upcoming WHO R&D Blueprint meeting ***Monkeypox research: What are the knowledge gaps and priority research questions?*** on 2 June 2022, 13:00–19:30 CEST. For more details and to register, please click here.

# # #

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

Media contact
Sarah-Jane Loveday
Director, Communications
M: +41 79 431 62 44
media@finddx.org

# # #