NEWS RELEASE

FDA Authorizes Quest Diagnostics' Proprietary Monkeypox Test for Emergency Use

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First lab-developed test specifically designed to detect Monkeypox virus DNA to receive emergency use authorization during the monkeypox public health emergency

SECAUCUS, N.J., Sept. 7, 2022 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced that it has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the company's lab-developed molecular diagnostic test to aid in the diagnosis of infection with the Monkeypox virus.

The EUA is the first granted to a commercially available monkeypox test in the United States. On September 7, the Department of Health and Human Services **declared** that the public health emergency countermeasures now extend to monkeypox testing.

"Quest is committed to developing high-quality diagnostic innovations to help respond to the monkeypox public health emergency," said Jay G. Wohlgemuth, M.D., Senior Vice President, R&D, Medical and Chief Medical Officer, Quest Diagnostics. "With this FDA emergency authorization, Quest is positioned to complement the response of public health laboratories and help fight the spread of the virus."

The Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR ("Quest Monkeypox PCR") is intended for the qualitative detection of Monkeypox virus (West African clade, clade II) DNA and non-variola Orthopoxvirus DNA in lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) in universal viral transport media from individuals suspected of Monkeypox virus infection by their healthcare provider. Test results are intended to be used in conjunction with patient history and other diagnostic information, and results should not be used as the sole basis of treatment or other patient management decisions.

Quest launched the Quest Monkeypox PCR test nationwide on **July 13, 2022**. The company performs the test at its advanced laboratories in San Juan Capistrano, Calif., and, beginning last week, Chantilly, VA, for ready access for providers and patients on both coasts of the United States. New York's Department of Health has approved the tests from both laboratories, enabling access for patients living in the state.

Developed with the understanding that viruses mutate, the Quest Monkeypox PCR test features the ability to detect two different DNA targets (Monkeypox and non-variola Orthopoxvirus DNA) to help protect against false negatives. On September 2, the Centers for Disease Control and Prevention issued a **Lab Alert** that certain monkeypox tests may fail to detect monkeypox infection when a rare deletion of the target gene (called tumor necrosis factor) occurs, and negative results for highly suspicious cases therefore require confirmation by the CDC or public health labs. The alert does not apply to the Quest Monkeypox PCR test, so Quest does not need to modify its test or refer specimens producing negative results to the CDC or public health labs for confirmation.

About Monkeypox and the Quest Monkeypox PCR Test

Monkeypox is a rare infectious disease typically occurring in parts of Africa. The West African clade (clade II) is the circulating virus in the current global outbreak. The first case of this virus in the United States was detected in May 2022. CDC recommends that anyone with monkeypox symptoms talk to their health care provider, even if they don't think they had contact with someone who has monkeypox.

The Quest Monkeypox PCR test uses swab specimens collected by healthcare providers, such as in physician offices and hospitals, from patients presenting with an acute generalized pustular or vesicular rash. Quest collects specimens for this test through its nationwide network of physician offices and hospital partners and also enables patients with suspected or confirmed monkeypox infection to visit its locations for phlebotomy blood draws and other non-swab specimen collections required for other types of laboratory testing.

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories;

- This product has been authorized only for the detection of nucleic acid from Monkeypox virus or other non-variola Orthopoxviruses, not for any other viruses or pathogens; and

- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the Monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola Orthopoxvirus, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §

360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

For more information, visit **www.QuestDiagnostics.com/monkeypox** or **http://newsroom.questdiagnostics.com/COVIDTestingUpdates**

About Quest Diagnostics

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve healthcare management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 50,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. **www.QuestDiagnostics.com**

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