Labcorp Receives FDA Emergency Use Authorization for Mpox PCR Test Home Collection Kit

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The first at-home mpox testing kit provides patients with convenience and privacy to test for mpox, supports physicians in detection and treatment

BURLINGTON, N.C., April 10, 2024 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, announced today the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for its Mpox PCR Test Home Collection Kit to aid in the diagnosis of infection with non-variola Orthopoxvirus, including the monkeypox virus that causes monkeypox, also known as mpox. The test is the first mpox at-home collection kit authorized by FDA and is available to physicians to order for patients 18 years of age or older who are suspected of mpox infection.

"The FDA's emergency authorization of Labcorp's Mpox PCR Test Home Collection Kit will enable us to play a vital role within the healthcare community in the early detection and management of mpox," said Dr. Brian Caveney, Labcorp's chief medical and scientific officer. "The collection kit reflects our ongoing commitment to providing critical diagnostic tools to physicians and accessible and convenient testing options to patients."

Physicians can order a test through Labcorp's provider interface platform for patients they suspect may be infected with the virus. Labcorp will send the test kit directly to patients for at-home collection. The kit includes detailed instructions for patients on correctly collecting a lesion swab, securing the sample in the provided collection tube, and preparing the package for return to an authorized laboratory for analysis.

Testing of specimens collected using the test kit will employ PCR (polymerase chain reaction) technology and will be conducted in authorized laboratories designated by Labcorp and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to meet the requirements for performing high-complexity testing criteria for the detection of non-variola *Orthopoxvirus* DNA. Results are electronically delivered to the prescribing physician and made available to the patient in Labcorp's patient portal at patient.labcorp.com. The company also aims to make the test available on its Labcorp OnDemand platform.

The authorization comes amid reported increases in mpox cases in the United States. According to the Centers for Disease Control and Prevention (CDC), there have been 511 mpox cases reported in 2024 through March 16, compared to fewer than 300 cases reported by late March 2023. Since the onset of the national 2022-2023 mpox virus outbreak, part of a larger global outbreak of human mpox caused by the West African clade of the monkeypox virus, the CDC notes more than 32,000 cases and 58 deaths have been reported nationally.

To learn more, visit https://www.labcorp.com/infectious-disease/mpox.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. This product has been authorized only for the collection and maintenance of lesion swab specimens as an aid in detection of nucleic acid from non-variola Orthopoxvirus, including monkeypox virus, not for any other viruses or pathogens. 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.

About Labcorp

Labcorp (NYSE: LH) is a global leader of innovative and comprehensive laboratory services that helps doctors, hospitals, pharmaceutical companies, researchers and patients make clear and confident decisions. We provide insights and advance science to improve health and improve lives through our unparalleled diagnostics and drug development laboratory capabilities. The company's more than 67,000 employees serve clients in approximately 100 countries, provided support for 84% of the new drugs and therapeutic products approved in 2023 by the FDA, and performed more than 600 million tests for patients around the world. Learn more about us at www.labcorp.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to statements with respect to the expected future availability of its services and products.

Each of the forward-looking statements is subject to change based on various important factors, many of which are beyond the company's control. These factors, in some cases, have affected and in the future (together with other factors) could affect the company's ability to implement the company's business strategy, and actual results could differ materially from those suggested by these forward-looking statements. As a result, readers are cautioned not to place undue reliance on any of the forward-looking statements.

The company has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. Further information on potential factors, risks and uncertainties that could affect operating and financial results is included in the company's most recent Annual Report on Form 10-K and subsequent Forms 10-Q, including in each case under the heading RISK FACTORS, and in the company's other filings with the SEC. The information in this press release should be listened to in conjunction with a review of the company's filings with the SEC including the information in the company's most recent Annual Report on Form 10-K, and subsequent Forms 10-Q, under the heading "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS"

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