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Laboratory Corporation of America Holdings (LabCorp) has announced the nationwide availability of testing for Zika virus using the RealStar Zika Virus RT-PCR Kit US from altona Diagnostics GmbH.

The test has received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) for the qualitative detection of Zika virus RNA in serum or urine (collected alongside a patient-matched serum specimen). It is intended to be used to aid in the diagnosis of Zika virus infection in individuals meeting clinical and/or epidemiological criteria for infection risk established by the Centers for Disease Control and Prevention (CDC).

"The Zika virus is a serious public health threat, and many people are concerned about the risk it presents to them and their families," said Mr David P King, LabCorp's chairman and chief executive officer. "Offering this new Zika virus test aligns with LabCorp's strategy to deliver world-class diagnostics that provide physicians and patients with information they need to achieve better health outcomes."

CDC clinical criteria for Zika virus infection testing include signs and symptoms associated with Zika virus infection. CDC epidemiological criteria for Zika virus infection testing include a recent history of residence in or travel to a geographic region with active Zika virus transmission at the time of travel, including for male sexual partners with such residence or travel history.

"Public health officials anticipate that the U.S. will become an area of active Zika virus transmission this year," said Dr Marcia Eisenberg, chief scientific officer for LabCorp Diagnostics. "LabCorp is pleased to support the effort to help identify and minimize human transmission of this disease in the US by offering the RealStar Zika Virus RT-PCR Kit US as a new tool that can help to improve health and improve lives."

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by CLIA High Complexity Laboratories and similarly qualified non-US laboratories and is only authorized for the duration of the declaration that circumstances exist justifying the EUA.

It is only authorized for the detection of RNA from Zika Virus and the diagnosis of Zika Virus infection, and not for any other viruses or pathogens. As required by FDA, LabCorp will report positive results of this test to CDC and other public health authorities, as may be appropriate. LabCorp will also report to altona Diagnostics any suspected occurrence of false positive or false negative results of which it becomes aware.