

FDA granted EUA to Siemens' Zika assay

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The US Food and Drug Administration (FDA) has granted [Siemens Healthcare](#) Diagnostics Inc. (Siemens) an Emergency Use Authorization (EUA) for its real-time PCR Zika Virus assay, the VERSANT Zika RNA 1.0 Assay (kPCR) Kit. With respect to Zika in vitro diagnostic tests, FDA has been authorized to issue EUAs to allow for use of unapproved medical products or unapproved uses of approved medical products when, among other circumstances, there are no adequate, approved, and available alternatives and certain additional criteria are met.

[Also read: RealStar Zika Virus Test](#)

"The FDA's emergency use authorization of the VERSANT Zika RNA 1.0 Assay (kPCR) Kit from Siemens can lead us one step closer to stopping the spread of the Zika virus," says Fernando Beils, Vice President, Head of Molecular Diagnostics, Siemens. "Being able to quickly diagnose patients will help physicians to more efficiently manage those affected."

The VERSANT Zika RNA 1.0 Assay (kPCR) Kit is capable of detecting the presence of Zika virus, which can be an earlier indicator of Zika virus infection than anti-Zika antibodies. The molecular test is validated for plasma, serum, and urine (collected alongside a patient-matched serum or plasma specimen) from individuals meeting CDC Zika virus clinical criteria and/or CDC Zika virus epidemiological criteria, and is designed to run on the Siemens VERSANT kPCR Sample Prep automated platform, along with several commercially available thermal cyclers. The assay must be run by laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

The VERSANT Zika RNA 1.0 Assay (kPCR) Kit has not been FDA cleared or approved and is only authorized for use for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection.