

APHL Summary of Commercially Available Zika Virus Assays with Emergency Use Authorization

- Updated October 7, 2016
- Assays Developed and Distributed by CDC Are Not Included in this Summary
- Performance Data for all EUA Assays Available on [FDA's Website](#) under "Labeling"

Assay	Date EUA Granted	Method	Available for Purchase by Other Laboratories?	Specimen Types Approved for Use*
Zika Virus RNA Qualitative Real-Time RT-PCR (Focus Diagnostics, Inc.)	April 28, 2016	Molecular; real time RT-PCR	No – testing with this assay only available through Quest	Serum
RealStar Zika Virus RT-PCR Kit U.S. (altona Diagnostics GmbH)	May 13, 2016	Molecular; real time RT-PCR	Yes	Serum and Urine (collected alongside a patient matched serum specimen)
Aptima Zika Virus Assay (Hologic, Inc.)	June 17, 2016	Molecular; TMA	Yes	Serum and plasma
Zika Virus Real-Time RT-PCR Test (Viracor-IBT)	July 19, 2016	Molecular; real time RT-PCR	No-testing with this assay is only available at Viracor-IBT's Laboratory	Serum, plasma and Urine (collected alongside a patient matched serum or plasma specimen)
VERSANT® Zika RNA 1.0 Assay (kPCR) kit (Siemens Healthcare Diagnostics, Inc.)	July 29, 2016	Molecular; real time RT-PCR	Yes	Serum, plasma and Urine (collected alongside a patient matched serum or plasma specimen)
xMap MultiFLEX Zika RNA Assay (Luminex Corporation)	August 4, 2016	Molecular; RT-PCR	Yes	Serum, plasma and Urine (collected alongside a patient matched serum or plasma specimen)
ZIKV Detect™ IgM Capture ELISA (InBios International, Inc.)	August 17, 2016	Serology; IgM Capture ELISA	Yes	Serum

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LightMix® Zika rRT-PCR Test (Roche Molecular Systems, Inc.)	August 26, 2016	Molecular; real time RT-PCR	Yes	Serum and EDTA Plasma
Sentosa® SA ZIKV RT-PCR Test (Vela Diagnostics USA, Inc.)	September 23, 2016	Molecular; RT-PCR	Yes	Serum , EDTA Plasma and Urine (collected alongside a patient-matched serum or plasma specimen)
Zika Virus Detection by RT-PCR Test (ARUP Laboratories)	September 28,	Molecular; RT-PCR	Yes	Serum , EDTA Plasma and Urine (collected alongside a patient-matched serum or EDTA plasma specimen)

*Testing for all specimen types should only be performed on individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated).