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Zika Virus Real-time RT-PCR

Test Code: 4800

Last updated 7/20/2016.

Clinical and Procedure

Clinical Utility

Zika Virus Real-time RT-PCR test is a real-time RT-PCR test intended for the qualitative detection of RNA from Zika virus in human plasma, serum or urine (collected alongside a patient matched serum or plasma specimen). Specimens are collected from individuals meeting Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or 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). Health care providers are strongly encouraged to collect serum/plasma specimens alongside other specimen types to provide additional opportunities for diagnosing Zika virus infection in cases when PCR tests are negative.

Procedure

Extraction of Zika virus nucleic acid from specimen, followed by combined reverse transcription of viral RNA and PCR amplification using real-time, RT-PCR methods. An internal control is added to ensure that extraction was performed correctly and that the RT-PCR reaction was not inhibited. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens. This test is only authorized 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 under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Specificity

Zika Virus RT-PCR does not cross-react with other viruses in the *Flaviviridae* family (including Dengue virus, Japanese encephalitis virus, West Nile virus and St. Louis encephalitis virus) or with other viruses known to cause similar clinical symptoms such as Chikungunya virus.

Turnaround Time

Same day (within 8 - 12 hours from receipt of specimen), Monday through Saturday.

Specimen Information

Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
plasma	4801	87798	Yes	2 mL (min. 0.5 mL)	Detected/Not Detected
Special Instructions - Collect 4-5 mL whole blood in EDTA or ACD tube. - Centrifuge (optional) and transfer 2 mL plasma to sterile, screw top tube. - Alternatively plasma can be shipped in the original collection tube without centrifugation. - Can be shipped at ambient or refrigerated temperature Monday through Friday. - Specimens shipped at ambient temperature must be received within 7 days of collection.					
serum	4810	87798	Yes	2 mL (min. 0.5 mL)	Detected/Not Detected
Special Instructions - Collect 4-5 mL whole blood in red top tube.					

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Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
- Centrifuge and transfer 2 mL serum to sterile, screw top tube. - Can be shipped at ambient or frozen temperature Monday through Friday. - Specimens shipped at ambient temperature must be received within 96 hrs of collection.					
urine	4802	87798	Yes	2 mL (min. 0.5 mL)	Detected/Not Detected

Special Instructions
- Collect in a sterile urinalysis container then transfer to sterile, screw top tube for shipment
- Can be shipped at ambient or refrigerated temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 7 days of collection.
- Do not freeze.
- When collecting urine, a patient-matched serum or plasma specimen is required for serological follow up testing of negative RT-PCR results, per the CDC testing algorithm.

Detected/Not Detected

Shipping
Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086.

Causes for Rejection
Whole blood frozen, specimens beyond their acceptable length of time from collection as listed in the specimen handling, or specimen types other than those listed.

Disclaimer
Specimens are approved for testing in New York only when indicated in the Specimen Information field above. The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.