



## Indiana State Department of Health

The Indiana State Department of Health Laboratories is now offering the Trioplex rRT-PCR assay, a molecular test for Zika, Dengue, and Chikungunya viruses. The Trioplex rRT-PCR assay has been authorized for the qualitative detection and differentiation of Dengue and Chikungunya viruses from serum and cerebrospinal fluid (CSF) or for Zika virus from serum, urine, CSF, and amniotic fluid. Submissions of CSF, urine, or amniotic fluid for Zika testing should be paired with a serum specimen from the same patient.

Patient screening and case approval will continue as per our previous guidance, and based on epidemiological data (i.e. travel to an endemic country and exhibiting symptoms or women who are asymptomatic but pregnant). Please follow these steps for case approval prior to submitting specimens:

1. Navigate to <http://www.in.gov/isdh> and click the banner at the top that says “Zika Virus.”
2. This will take you to the main Zika page. Click the link that says “For Providers”.
3. This link will take you to the indications and instructions for Zika virus testing. Providers should follow the listed steps, which include reviewing if the patient meets Zika testing criteria, and faxing the “ISDH Zika Virus Authorization Form” to 317-234-2812.
4. You will receive a response within one (1) business day.

Due to the emerging and urgent need for enhanced Zika virus diagnostics, the Trioplex rRT-PCR Assay was made available by an Emergency Use Authorization (EUA) from the FDA, and is exempt from some of the regulations and validations of other assays. As some of the inherent variability of a EUA-assay may not be fully understood by patients, we are intending to fill this gap by way of a notification waiver. ***Clinicians will need to describe the risks associated with this test to all patients for whom a specimen is submitted to the ISDH Laboratories. The signed waiver should accompany the submitted specimen. No testing will proceed at the ISDH Laboratories without prior receipt of a patient-signed waiver.***

Additional information, including specimen collection and submission guidelines, test interpretation guidelines, the Patient Waiver, and a FAQ document are available, and will be provided through the test approval process.

### Indiana State Department of Health Zika Testing Process

