



## Laboratory Services

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## Zika Antibody Testing

- Specimen: Serum or cerebrospinal fluid (CSF) specimen
- IgM antibody
  - Starts to develop 7 days after exposure or onset of symptoms
  - Present from 1-12 weeks after exposure or onset of symptoms
- Negative results do not need confirmatory testing
- Positive, Equivocal & Indeterminate IgM results require confirmatory testing:
  - Viral RNA detection by polymerase chain reaction (PCR)
  - Plaque reduction neutralization testing (PRNT) is performed at Centers for Disease Control and Prevention (CDC) Fort Collins or at a PRNT designated laboratory.
    - PRNT is used to quantify the titer of neutralizing antibody for a virus.
    - Zika virus and Dengue virus PRNT testing is performed simultaneously for confirmatory result interpretation.



## Zika PCR Testing

- Specimen: Serum and the following:
  - Urine, CSF, or amniotic fluid
    - Urine is the best specimen for PCR testing since there is a high viral load.
- Detects Zika virus RNA
  - Viral RNA detectable in serum during the acute phase of infection. The acute phase lasts approximately 7 days following symptom onset or exposure.
  - Viral RNA is detectable in urine up to 14 days post onset of symptoms or exposure.
  - If pregnant, the virus may be detectable in serum and urine for a prolonged period of time.
- Positive results do not need confirmatory testing
- Negative results require a convalescent serum specimen for IgM antibody testing if clinical suspicion is warranted.
  - Serum needs to be collected >14 days after symptom onset or exposure.



## Symptomatic Individual

- Specimen requirement:
  - Urine and Serum
- Testing:
  - <14 days after onset of symptoms
    - Test serum and urine by PCR
      - » If PCR is positive for Zika virus then testing is complete
      - » If PCR is negative then convalescent serology is needed if clinical suspicion is warranted.
  - >14 days after onset of symptoms (< 12 weeks of onset)
    - Test serum for IgM antibody to Zika virus
      - Negative – Testing is complete
      - Positive – Confirmatory testing is required
        - » If PCR is positive for Zika virus then testing is complete
        - » If PCR is negative then Zika PRNT is required



## Asymptomatic Pregnant

- Specimen requirement:
  - Urine and Serum
- Testing:
  - <14 days after return from travel or exposure
    - Test serum and urine by PCR
  - >14 days after return from travel or exposure (< 12 weeks after travel return or exposure)
    - Test serum for IgM antibody to Zika virus
      - Negative – Testing is complete
      - Positive – Confirmatory testing is required
        - » If PCR is positive for Zika virus then testing is complete
        - » If PCR is negative then Zika PRNT is required



## Zika Commercial Tests

All Zika tests are under an Emergency Use Authorization (EUA) by the Federal Drug Administration (FDA)

### Antibody Tests

- CDC Zika MAC-ELISA: Performed at UPHL
- InBios International, Inc. ZIKA Detect™ IgM Capture ELISA

FDA site accessed 8/30/2016

**Zika Commercial Tests** 

**PCR Tests**

- CDC Trioplex rRT-PCR: Performed at UPHL
  - Zika: Serum, urine, CSF & amniotic fluid
  - Dengue & Chikungunya: Serum
- Luminex XMAP® MultiFLEX Zika RNA Assay
- Siemens Healthcare Diagnostics VERSANT® Zika RNA 1.0 Assay
- Roche Molecular Systems LightMix® Zika rRT-PCR Test
- Viracor-IBT Laboratories, Inc. Zika Virus Real-Time RT-PCR Test
- Hologic Inc. Aptima Zika Virus Assay
- Altona Diagnostics GmbH RealStar Zika Virus RT-PCR
- Focus Zika Virus RNA Qualitative Real-Time RT-PCR

FDA site accessed 8/30/2016 7

**Zika Resources** 

**EUA Fact Sheets:**  
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm#zika>

- Healthcare Providers
- Patients
- Pregnant Women

**FDA Zika Information:**  
<http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm#FDAinfo>

**CDC Zika Information:**  
<http://www.cdc.gov/zika/laboratories/index.html>

**UDOH Zika Information:**  
<http://health.utah.gov/epi/diseases/zika/>

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**Contact Information** 

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