



Florida Department of Health

Zika Virus  
Laboratory Diagnosis

Focus Area: Collection, Packaging  
and Shipping of Laboratory  
Specimens

Guidance document number 2016-01

Zika Virus Diagnostic Specimen Collection, Packaging and Shipping Guidance  
for Laboratories and County Health Departments

Version 2.0 April 18, 2016

Summary:

- **Authorization:** Contact your local County Health Department for authorization prior to collecting and shipping diagnostic specimens for Zika virus testing. Testing requires prior approval before specimen submission.
- **Specimen Selection:** Specimens for rRT-PCR are preferred. Serum for IgM testing can also be collected.
- **Specimen Collection:** Specimens for rRT-PCR testing should be collected within the first 21 days of illness: serum (**2 ml serum/red or red/grey marble tiger top tube**) AND urine sample collected (**1 - 2 ml, 5 ml max, in a sterile container**) Serum and urine samples are preferred until we can evaluate whether using a particular sample type consistently improves test sensitivity.
- **Packaging: Transport by Commercial Carrier:** It is recommended that all suspect Zika virus diagnostic specimens be packaged according to IATA/DOT Packaging Instructions 650 for Biological substance, Category B agents which requires specimens be packed in a basic triple packaging system with a primary watertight container wrapped with absorbent material, secondary watertight container and an outer shipping package.
- **Packaging: Transport by Local Courier:** As above, specimens should be packaged in a basic triple packaging system which consists of a primary watertight container wrapped with absorbent material, secondary watertight container and an outer shipping package.
- **Laboratory Requisition:** PCR testing for Zika virus at BPHL can be ordered using test code 1680 (Arbovirus PCR) in the virology section of the standard BPHL form and write "Zika PCR" in the comment box. IgM serologic tests can be ordered using test code 1500 Arbovirus IgM Antibody. Be sure to include onset, sample collection date, pregnancy status (female patients), travel country/territory and dates, and whether fever was reported.

- **Shipping to Jacksonville BPHL:**

Bureau of Public Health Laboratories-Jacksonville  
1217 N. Pearl Street  
Jacksonville, FL 32202  
Attention: Valerie Mock

**For Additional Information:** Contact Valerie Mock at 904-791-1539 or 904-637-9284  
Alternate contact Pamela Colarusso at 904-791-1540



- **Shipping to Tampa BPHL:**

Bureau of Public Health Laboratories-Tampa  
3602 Spectrum Blvd  
Tampa, FL 33612  
Attention: Lea Heberlein-Larson

**For Additional Information:** Contact Lea Heberlein-Larson at 813-974-5990  
or 813-967-0330.

Alternate contact Marshall Cone at 813-974-0134 or 813-363-0707



- Specimens delivered to Miami BPHL will be shipped overnight to Tampa BPHL.

## Authorization

- Contact your local County Health Department prior to collecting any specimens from suspect Zika cases. Testing requires prior approval before specimen submission.

## Specimen Selection

- Specimens for rRT-PCR are preferred. Serum for IgM testing can also be collected.
- For asymptomatic pregnant women only, serum for IgM is preferred.

## PCR testing of serum and urine; or from a birth CSF from the infant, amniotic fluid, birth cord blood (1 – 2 ml), and fresh placenta (1 - 2 cm<sup>3</sup>) at Bureau of Public Health Laboratories (BPHL)-Tampa or BPHL-Jacksonville

- Sample collected within the first 21 days of illness: serum (**2 ml serum/red or tiger top tube**) AND urine sample collected (**1 - 2 ml, 5 ml max, in a sterile container**). Serum and urine samples are preferred until we can evaluate whether using a particular sample type consistently improves test sensitivity.
- Sample from asymptomatic pregnant women: serum only (**2 ml serum/red or tiger top tube**)

- **Depending on BPHL sample volume**, samples meeting the requirements for Zika fever PCR testing at BPHL will also be considered for testing for dengue and chikungunya **if the patient reported fever**.
- **Depending on BPHL sample volume**, samples collected during the acute stage of illness and meeting standard requirements for dengue and chikungunya testing will also be tested for Zika virus by PCR if travel to an area with Zika virus activity is reported.
- Other specimen types from a birth such as infant CSF, amniotic fluid, birth cord blood (1 – 2 ml), and fresh placenta (1 - 2 cm<sup>3</sup>) may be tested with the appropriate approvals from the health department. Note: formalin fixed placenta may also be collected for pathology testing as CDC.

### **IgM antibody and serum neutralization testing:**

- PCR is the definitive test. If PCR is positive on **serum**, serologic testing is not necessary. If serum is negative but urine is PCR positive, please request IgM ELISA and if necessary attempt to collect a convalescent sample.
- Acute serum samples should be collected ≤8 days after illness onset; convalescent serum samples should be collected >8 days after illness onset. **(2 ml serum/red or red/grey marble tiger top tube for each sample)**
- Cross-reaction with related flaviviruses (e.g. dengue, West Nile, yellow fever, Japanese encephalitis viruses) on serological tests is common and results may be difficult to interpret.
- Additional serological testing such as serum neutralization can be performed at CDC to provide more definitive results.
- Commercial testing for Zika virus is currently not available.

### **Specimen Collection**

- Specimen collection should be performed following standard precautions. Wear appropriate personal protective equipment (PPE) at all times while collecting and handling specimens.
- Specimens for rRT-PCR: Serum, urine, and **from a birth CSF from the infant, amniotic fluid, birth cord blood (1 – 2 ml), and fresh placenta (1 - 2 cm<sup>3</sup>)** may be used. Use sterile containers for urine, CSF, amniotic fluid, birth cord blood, and fresh placenta specimens and seal or cap container(s) securely to avoid leakage and loss of specimen.
- Specimens for IgM: Collect blood into tubes without additives-either a plain, red-top tube or a serum separator tube (red/gray marble tiger top).
- Please notify BPHL (see below for contact information) before submitting a high priority sample (pregnant women with fetal abnormalities, infant birth defects or poor pregnancy outcomes after the first trimester of pregnancy with history of travel during pregnancy; suspect Guillain-Barre Syndrome patients with history of travel in the two weeks prior to illness onset; or suspect local cases).
- Ship immediately on cold packs. If samples cannot be shipped immediately, store samples at 4°C until shipment. **DO NOT FREEZE**
- From a birth formalin fixed placenta may also be collected in a sterile container for testing at the CDC pathology lab. Seal or cap container(s) securely to avoid leakage and loss of specimen. Store fixed placenta only at room temperature.

## **Packaging requirement: Transport by Commercial Carrier**

### General Requirements

- We recommend that you package the specimens as a Category B agent using IATA/DOT Packaging Instructions 650 for Category B Agents which requires specimens be packed in a basic triple packaging system with a primary watertight container wrapped with absorbent material, secondary watertight container and an outer shipping package.
- Enclose an itemized list of contents between the secondary packaging and the outer packaging.
- Package on cold packs, with the exception of fixed placenta. Fixed placenta is shipped at room temperature.

### Inner Packaging Requirements

- Primary receptacle(s) must be watertight.
- Secondary receptacle must be watertight.
- An itemized list of the contents enclosed between the secondary receptacle and the outer packaging (overpack).
- Absorbent material must be placed between the primary receptacle(s) and secondary receptacle and be of sufficient quantity to absorb the entire contents of the primary receptacle(s).

### Outer Packaging Requirements

- Package must be rigid.
- Package must be properly labeled with the UN 3373 marking, the shipping name, “Biological Substance, Category B”, and orientation labels.
- Package must pass required testing.

## **Packaging Requirements: Transport by Local Courier**

Package specimens in combination packaging according to 49 CFR 173.6(a)(4).

<http://www.gpo.gov/fdsys/pkg/CFR-2011-title49-vol2/pdf/CFR-2011-title49-vol2-sec173-6.pdf>

### General Packaging Requirements

- Packaging must coincide with 29 CFR 1910.1030 and specimens should be packed in a basic triple packaging system with a primary watertight container wrapped with absorbent material, secondary watertight container and an outer shipping package.
- Enclose an itemized list of contents between the secondary packaging and the outer packaging.
- Package on cold packs, with the exception of fixed placenta. Fixed placenta is shipped at room temperature.

### Inner Packaging Requirements

- Primary receptacle(s) must be watertight.
- Secondary receptacle must be watertight.

- An itemized list of the contents enclosed between the secondary receptacle and the outer packaging.
- Absorbent material must be placed between the primary receptacle(s) and secondary receptacle and be of sufficient quantity to absorb the entire contents of the primary receptacle(s).

#### Outer Packaging Requirements

- Package must be rigid, with strong packaging, to secure against shifting.

#### Laboratory Requisition

- PCR testing for Zika virus at BPHL can be ordered using test code 1680 (Arbovirus PCR) in the virology section of the standard BPHL form and write “Zika PCR” in the comment box.
- IgM serologic tests can be ordered using test code 1500 Arbovirus IgM Antibody. **Be sure to include onset, sample collection date, pregnancy status (female patients), travel country/territory and dates, and whether fever was reported.**

**Ship Specimens To:** the appropriate location of the Bureau of Public Health Laboratories, addresses are located on page 2. Deliver or ship samples immediately, at least by next day mid-morning delivery.

**Notification:** On shipment of a specimen for a suspect Zika patient to BPHL, please notify Valerie Mock with the Jacksonville BPHL (see below for contact information) or Lea Heberlein-Larson with the Tampa BPHL (see below for contact information) Provide the shipping tracking number if being shipped commercially.

#### **For Additional Information:**

**On Submitting Specimens for Zika Testing:** Contact your local County Health Department.

#### **Contacts for Laboratory Questions:**

##### ***Jacksonville***

Valerie Mock, Bureau of Public Health Laboratories at 904-791-1539 or 904-637-9284; Pamela Colarusso at 904-791-1540

##### ***Tampa***

Lea Heberlein-Larson, Bureau of Public Health Laboratories at 813-974-5990 or 813-967-0330; Marshall Cone 813-974-0134 or 813-363-0707

#### **For more information on DOT shipping regulations:**

[https://hazmatonline.phmsa.dot.gov/services/publication\\_documents/Transporting%20Infectious%20Substances%20Safely.pdf](https://hazmatonline.phmsa.dot.gov/services/publication_documents/Transporting%20Infectious%20Substances%20Safely.pdf)