



Florida Department of Health

Bureau of Public Health Laboratories

Zika Testing – Frequently Asked Questions

1. Do submissions to BPHL require prior approval by the Bureau of Epidemiology?
 - a. *Yes, contact the epidemiology department at your local county health department.*

2. What specimen types do you accept for testing?
 - a. *Serum*
 - b. *Urine*
 - c. *Whole blood (EDTA)*
 - d. *Cerebrospinal fluid (CSF)*
 - e. *Amniotic fluid*

NOTE: Serum is the preferred diagnostic specimen. Urine, whole blood, CSF, and amniotic fluid may only be tested alongside a patient-matched serum specimen.

3. If the above specimen types or a patient-matched serum specimen are unobtainable, will BPHL still perform testing?
 - a. *If it is a high priority case (pregnant woman with fetal abnormalities, infant birth defect or poor pregnancy outcomes after the first trimester of pregnancy with history of travel during pregnancy; suspect Guillain-Barre Syndrome patient with history of travel in the two weeks prior to illness onset; or suspect local case), contact your local county health department to seek guidance.*

4. How long after onset of symptoms can the specimens be collected?
 - a. *Less than 14 days (serum, urine, whole blood, CSF)*
 - b. *If 14 days or more, serum only*
 - c. *Not applicable to asymptomatic pregnant women or individuals with no travel, all appropriate specimens can be collected at any time after travel or exposure*

5. What are the minimum volumes that the laboratory needs for testing, if there is a problem getting the requested volumes:
 - a. Serum: 1-2 mls
 - b. Urine: 1-2 mls (max 5 mls)
 - c. Whole blood (EDTA): 1-2 mls (max 5 mls)
 - d. CSF: 0.5-2 mls
 - e. Amniotic fluid: 1-2 mls
 - f. Infants: volumes listed above, but if this is not possible a minimum of 0.5 mls

6. For serum, what kind of blood draw tube should be used?
 - a. Serum separator tube (red/grey tiger top tube), centrifuged prior to shipment.
 - b. If a serum separator tube is not available, use tubes without additives-a plain red-top tube. Centrifuge the tube and pour off the serum into a sterile tube.

7. For amniotic fluid, what kind of container should we use?
 - a. Use a sterile leak-proof container. Please ship no more than 5 mls of fluid and ensure that the container lid is secured completely to avoid leakage. Also ship the container upright to avoid spillage. Place each container in a separate zip-seal bag.

8. Will the BPHL provide sample collection supplies?
 - a. No, the sample provider is responsible for obtaining collection supplies.

9. Will you accept urine in specimen containers containing additives or preservatives?
 - a. No, just use a sterile leak-proof container. Please ship no more than 5 mls of urine and ensure that the container lid is secured completely to avoid leakage. Also ship the container upright to avoid spillage. Place each container in a separate zip-seal bag.

10. Can urine alone be submitted?
 - a. No, a serum sample must also be submitted.
 - b. If a serum is unobtainable and the patient is a high priority case (pregnant woman with fetal abnormalities, infant birth defect or poor pregnancy outcomes after the first trimester of pregnancy with history of travel during pregnancy; suspect Guillain-Barre Syndrome patient with history of travel in the two weeks prior to illness onset; or suspect local case), contact your local county health department to seek guidance.

11. Can whole blood alone be submitted?
- No, a serum sample must also be submitted.*
 - If a serum is unobtainable and the patient is a high priority case (pregnant woman with fetal abnormalities, infant birth defect or poor pregnancy outcomes after the first trimester of pregnancy with history of travel during pregnancy; suspect Guillain-Barre Syndrome patient with history of travel in the two weeks prior to illness onset; or suspect local case), contact your local county health department to seek guidance.*
12. Can CSF alone be submitted?
- No, a serum sample must also be submitted.*
 - If a serum is unobtainable and the patient is a high priority case (pregnant woman with fetal abnormalities, infant birth defect or poor pregnancy outcomes after the first trimester of pregnancy with history of travel during pregnancy; suspect Guillain-Barre Syndrome patient with history of travel in the two weeks prior to illness onset; or suspect local case), contact your local county health department to seek guidance.*
13. Can amniotic fluid alone be submitted?
- No, a serum sample must also be submitted.*
 - If a serum is unobtainable and the patient is a high priority case (pregnant woman with fetal abnormalities, infant birth defect or poor pregnancy outcomes after the first trimester of pregnancy with history of travel during pregnancy), contact your local county health department to seek guidance.*
14. How should we store specimens prior to shipment?
- 4°C is best for storage*
15. Where/how do we store specimens over the weekend for shipment Monday?
- Specimens can be stored at 4°C until shipment. DO NOT FREEZE specimens.*
16. How should we ship specimens to the BPHL?
- Overnight, Category B*
17. Will the BPHL provide Category B shipping materials?
- No, the sample provider is responsible for obtaining shipping materials.*

18. Where do we ship specimens?

Unless otherwise instructed by the Bureau of Epidemiology,

- a. *The following counties should ship to BPHL-Tampa*
 - i. Bay, Calhoun, Charlotte, Citrus, Collier, Dade, Desoto, Escambia, Glades, Gulf, Hardee, Hendry, Hernando, Highlands, Hillsborough, Holmes, Jackson, Lake, Lee, Levy, Manatee, Monroe, Okaloosa, Osceola, Pasco, Pinellas, Polk, Santa Rosa, Sarasota, Sumter, Walton, Washington
- b. *The following counties should ship to BPHL-Jacksonville*
 - i. Alachua, Baker, Bradford, Brevard, Broward, Clay, Columbia, Dixie, Duval, Flagler, Franklin, Gadsden, Gilchrist, Hamilton, Indian River, Jefferson, Lafayette, Leon, Liberty, Madison, Marion, Martin, Nassau, Okeechobee, Orange, Palm Beach, Putnam, Seminole, St Johns, St Lucie, Suwannee, Taylor, Union, Volusia, Wakulla
- c. *The following counties can deliver by local courier to BPHL-Miami*
 - i. Dade, Broward

19. Will BPHL pay for the shipping costs associated with sending the specimens?

- a. *No, the sample provider is responsible for paying for shipping costs.*

20. What testing is being performed at BPHL?

- a. *BPHL at Jacksonville, Miami, and Tampa can perform real-time PCR on the specimens using the Trioplex Real-Time RT-PCR Assay.*
- b. *BPHL at Jacksonville and Tampa can perform IgM ELISA on the samples using the Zika MAC-ELISA.*
- c. *BPHL-Miami will forward specimens requiring IgM ELISA to BPHL-Tampa or BPHL-Jacksonville as appropriate.*

21. What is the Trioplex Real-Time RT-PCR Assay?

- a. *This assay has a FDA Emergency Use Authorization (EUA), was developed by the CDC, and detects RNA from dengue, chikungunya, and Zika viruses.*
- b. *BPHL fully switched to this assay from a Laboratory Developed Test (LDT) in December 2016.*

22. Will all acceptable specimen types also be tested for dengue and chikungunya with the Trioplex assay?

- a. *No. Serum, whole blood, and CSF are approved specimens types for Zika, chikungunya, and dengue testing. All of these will also be tested for dengue and chikungunya. Urine and amniotic fluid will only be tested for Zika.*

23. What is the Zika MAC-ELISA?
- This assay has a FDA Emergency Use Authorization (EUA), was developed by the CDC, and detects IgM antibodies to Zika virus.*
24. How are the PCR and IgM ELISA results reported?
- PCR – Zika virus detected; Zika virus not detected; Zika virus inconclusive. Note: a prior assay reported equivocal results, therefore older results may have equivocal results reported.*
 - ELISA –IgM Positive; IgM negative; IgM equivocal; IgM indeterminate*
25. What is the TAT for PCR testing once a sample is received at the lab?
- 24-48 hours*
26. What is the TAT for IgM ELISA testing once a sample is received at the lab?
- 1-5 days*
27. How are the results reported?
- Results are submitted back to the submitting provider and epidemiologist at the local county health department.*
28. What testing is being performed by CDC?
- Additional confirmatory testing of serum when warranted such as Plaque Reduction Neutralization Test (PRNT, also referred to as serum neutralization).*
 - Tissues related to a birth: placenta and fetal membranes, umbilical cord, brain and spinal cord, and solid organs (heart, lung, liver, kidneys, skeletal muscle, eyes, bone marrow)*
29. Should the tissues be fixed?
- CDC requests formalin fixed and/or paraffin embedded tissues. Submission of frozen tissues may be considered on a case by case basis.*
 - Fixed tissues should be stored and shipped at room temperature, do not freeze.*
 - Frozen tissues should be shipped with dry ice.*
30. Is pre-approval required prior to submission of any tissue specimens to CDC?
- Yes, health care providers must notify their local county health department to obtain pre-approval before they are collected and sent to BPHL. Specimens can ONLY be sent to CDC from BPHL.*