



County Health Department (CHD) Guidance on Testing Pregnant Women for Zika Virus Infection

Version 4.0 (August 7, 2017) Green text indicates revisions

DOH: www.flhealth.gov/zika

CDC: www.cdc.gov/zika/

FloridaHealth.gov • Florida Department of Health

Summary

- To ensure disease reporting and a prompt mosquito control response, health care professionals should notify their County Health Department (CHD) if a Zika virus infection is suspected per Florida Administrative Code, Chapter 64D-3. Waiting for laboratory results delays mosquito control actions.
- Providers should order Zika tests through commercial labs as they would order any other tests for their patients and do not need to contact the CHD to receive **pre-approval** for testing in the commercial sector but providers should notify the CHD as soon as Zika virus infection is suspected.
- A Person Under Investigation (PUI) record should be created by CHDs in Merlin for all individuals being tested who are suspected of Zika virus infection. (PUI and case information is used to assess CHD patient load and appropriate corresponding funding allocations.)
- Testing is available at BPHL for those who meet DOH testing criteria (suspect local or congenital cases) OR those who cannot obtain testing through a commercial laboratory, such as those that are uninsured or underinsured.
 - **CHD staff should consult with state Bureau of Epidemiology staff when notified of suspected local cases.**
 - If a pregnant woman needs testing or insists on testing (even if she doesn't fall into the DOH guidance for testing) and cannot get it through a provider at a commercial laboratory, the pregnant woman can receive testing through DOH. Testing for patients with insurance should continue to be billed to their insurance company.
 - When a CHD functions as the provider, the CHD should follow the attached algorithm "CHD: Algorithm for determining *where to submit specimens* from pregnant women for testing when the CHD is serving as the provider."

I. Pregnant women should be tested for Zika in accordance with the most current DOH and CDC guidance.

- Guidance related to potential exposures outside the U.S.:
<https://www.cdc.gov/zika/geo/countries-territories.html>
- Guidance related to potential exposures in Miami-Dade County:
<https://www.cdc.gov/zika/intheus/florida-update.html>
- Guidance related to potential exposures in Brownsville, Texas
<https://www.cdc.gov/zika/intheus/texas-update.html>

II. Pregnant women *without* likely exposure to Zika virus

1. Pregnant women without exposure to Zika virus (e.g., no travel history to areas with active transmission, no sexual contact with a partner who lives in or traveled to an area with active transmission, etc.) and without symptoms of disease should be counseled on the risks and benefits of testing (e.g. false positives and negatives) and reassured that testing is unnecessary at that time. For more information see:
<https://www.cdc.gov/zika/hc-providers/testresults.html>
1. The woman should be counseled on how to prevent Zika virus infection and to seek testing if she becomes exposed in the future and/or develops symptoms of disease.
2. If the pregnant woman insists on testing, then she can be tested.
 - a. Pregnant women with a private provider and insurance should be tested commercially, as coordinated by their provider and without involvement of the CHD.
 - b. Pregnant women with the CHD as their provider and/or providers for those who are uninsured or underinsured, may contact the CHD to coordinate testing at no cost to the patient.
 - CHDs may require appointments to be made for specimen collection, however they must be timely, within a week of the request.
 - Testing is available for all pregnant women who request a test regardless of residence.
 - There is no limit to the number of tests a pregnant woman can receive; and there is no requirement to verify pregnancy status.

III. Assessment questions – for all pregnant women with testing coordinated by the CHD

- Ask for symptoms within the last 14 days.
 - Collect information on Zika specific symptoms: fever, rash, joint pain/arthralgia, or reddened eyes/conjunctivitis, including date of onset.
- Ask for travel history outside the continental US during the pregnancy. This information assists with test selection and interpretation.
 - Collect name of countries and US territories visited (US Virgin Islands and Puerto Rico) and dates of travel.
 - Ask for travel history to **areas of active local transmission *should those be declared.***
- Ask for gestational age (in weeks) and anticipated due date.
- Responses to questions should be recorded on the paper Zika specific DH 1847 or in HMS at the time the electronic laboratory order (ELO) in Emdeon is placed; this ensures appropriate testing of priority samples when received at the laboratory. **Those specimens *without* symptoms or exposure histories recorded on Zika specific DH 1847 or HMS will be tested *after* priority specimens. Submit one DH 1847 (list both specimens on one form.)**

IV. Specimen collection

1. Specimen collection and processing differs depending on which laboratory (BPHL or commercial) the specimens are to be submitted for testing.
 - If the CHD is functioning as the provider, use the “CHD Algorithm A: Algorithm for determining *where to submit specimens* from pregnant women for testing when the CHD is serving as the provider.”

A. Specimen collection and transport - **BPHL**

o Collect **BOTH** specimens: Urine and Serum

1. **Specimen 1: Urine** specimen (1-3ml). **Use of inappropriate urine containers can result in loss of specimen and delays in testing.**
 - If urine is collected in a cup, urine should be transferred to a sterile tube with a secure closure to prevent leakage in transport.
 - a. Label tube as urine
 - b. Label with patient name and date of birth (DOB)
 - c. Place sample/tube in its **own biohazard Ziploc** bag. Include a paper towel or equivalent to absorb any leaking fluid.
 - d. **Refrigerate**. Ship cold within the same or next day.



Use BD vacutainer urine collection tube, BD #364979, Fisher Scientific catalog #14-375-138

Collect in urine cup and **transfer to a sterile tube** for shipping.

Do not submit urine in urine collection cups; they leak during transport.

2. **Specimen 2: Serum** specimen in **red or tiger** top tube (1-2ml).
 - a. Label tube as serum
 - b. Label with patient name and DOB
 - c. Spin before sending; transfer serum to a sterile container before shipping if red top or other tube type without separator gel.
 - d. Place tube in its **own biohazard Ziploc** or equivalent bag. Include a paper towel or equivalent to absorb any leaking fluid.
 - e. **Refrigerate**. Ship cold within the same or next day.
 - Ensure shipments will be received during the week M-F unless special arrangements have been made with BPHL virology.
 - If the sample will not be received at BPHL within 5 days of collection; the sample must be **FROZEN**. Serum should be aliquoted into a clean, sterile container (without separator gel or preservatives) and **FROZEN** until shipped. **Do not freeze in the same tube that has the red blood cell component. FROZEN serum must be shipped on dry ice.** Refrigerated urine cannot be shipped in the same dry ice package.



OR



3. **Place both separately bagged specimens into a 95kPa pressure compliant bag** or other pressure compliant container.
4. **Ship specimens on cold packs. Refrigerate do NOT freeze.** Specimens should be shipped upright. **Ensure shipments will be received during the week M-F unless special arrangements have been made with BPHL virology.**
5. Follow all packaging requirements for a Category B (UN3373) agent shipment using IATA/DOT Packaging Instructions 650 which requires specimens be packed in a basic triple packaging system. Individuals packaging specimens should have received training.



- Place the printed completed HMS electronic laboratory order form AND completed Zika specific DH 1847 inside the specimen shipping box. Submit one DH 1847.
 - Order both ZIKV PCR and ZIKV IgM antibody
 - BPHL test numbers: 1537 Arbo Zika RT-PCR 1539 Arbo Zika IgM ELISA



6. **Orders should be placed in HMS when testing is to be performed at BPHL and the paper DH 1847 should also be completed.** See V. HMS Guidance for Zika Test Ordering. HMS ELO helps improve the BPHL turnaround time.
 - a. **Place the printed completed HMS ELO order form and completed DH 1847 (with complete patient information) inside the specimen shipping box along with the labeled specimens.** One DH 1847 should be submitted for both specimens.
 - b. **In HMS** order both ZIKV PCR and ZIKV IgM antibody.
 - BPHL test numbers: 1537 Arbo ZIKA RT-PCR and 1539 Arbo Zika IgM ELISA
 - c. **Use of DH 1847.** The CHD should complete and submit the paper DH 1847 in addition to placing the order in HMS. If the order is not placed via HMS, the provider should use the Zika specific DH 1847. Contact the CHD to receive a Merlin # for a PUI and record the Merlin # on the DH 1847 to indicate CHD approval; answer Zika specific questions (travel history, symptoms, and pregnancy status). Specimens received by BPHL *without* a Merlin # or responses to Zika specific questions on the DH 1847 will experience processing delays. Only one DH 1847 should be used for both specimens.
 - Zika specific fillable DH 1847: http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/_documents/laboratory-specimen-submission-form-dh1847-for-zika-testing.pdf

B. Specimen collection and transport – Quest Diagnostics (two options) Testing at Quest Diagnostics replaces the previous LabCorp testing options.

OPTION 1-QUEST: SPECIMEN COLLECTION AT A QUEST LOCATION. Preferred.

- CHDs have the option to send patients to a **QUEST Diagnostics Patient Service Center (PSC)** for specimen collection. This option is suggested as preferred to ensure **QUEST** specimen collection and shipping requirements are met. To ensure a smooth process, consider contacting your local **QUEST** office and speaking with the manager the first time this option is used to ensure they are familiar with the program and know who to contact if any questions arise.
- **To ensure a smooth process, consider contacting your Quest Diagnostics sales representative at 1.866.MYQUEST (1.866.697.8378) to help answer any questions you may have.**
 1. Evaluate patient and collect screening questions.
 2. Complete **QUEST** test order via HMS ELO. See V. HMS guidance for ordering Zika testing.
 - a. Order collection for **both** serum and urine. Both serum and urine should be collected on the same day.
 - Order both ZIKV PCR and ZIKV IgM antibody:
 - **Zika Virus RNA, Qualitative, Real-Time RT-PCR Panel, Serum/Urine, Test Code 94221(X)**
 - **Zika Virus Antibody (IgM), MAC-ELISA, Test Code 94264(X)**
 - b. **Select Order Type – PSC and print the HMS Emdeon laboratory requisition form within HMS.**
 - c. Provide printed specimen requisition form to patient. The patient **MUST** take the printed requisition form **WITH THEM** to **QUEST** at the time of their visit.
 - d. Instruct patient to go to a **QUEST Diagnostics Patient Service Center.**
 - **Visit QuestDiagnostics.com to find Patient Service Center locations.**
 - **Link address: QuestDiagnostics.com/Appointment**
 - A patient can go to any **Quest Diagnostics Patient Service Center** location.
 - A patient can go on line to schedule an appointment at a **Quest Diagnostics Patient Service Center** facility **AFTER** they have their printed **HMS Emdeon laboratory requisition form.**
 - Patients can also go to a **Quest Diagnostics Patient Service Center** location without scheduling an appointment. Walk-in wait times will apply.

The screenshot shows the Quest Diagnostics website interface. At the top left is the Quest Diagnostics logo. To the right of the logo are navigation links: "Our Company", "Make an Appointment", "News & Media", "Social Media", "En Español", and "MyQuest™ Patient Portal". A search bar with a "Go" button is located to the right of these links. Below the search bar is a horizontal navigation menu with the following items: "Home", "For Patients" (circled in red), "For Physicians & Hospitals", "For Companies & Organizations", and "Contact Us". Under the "For Patients" menu, there are four columns of links:

- Locations/Appointments:** "Make an Appointment" (circled in red), "Cancel / Change / Confirm Appointment", "Find a Location", "Tell us about your recent visit", "Take our survey".
- Billing Information & Customer Service:** "Pay Your Invoice", "Check Invoice Status", "FAQs for Billing", "Update Insurance", "Manage Paperless Billing Options", "See Insurance Providers List", "Contact Customer Service", "Take Our Billing Survey".
- What We Offer:** "Diagnostic Testing A-Z", "Requesting a Lab Test", "Preparing for a Lab Test", "Keeping Drug Therapy Safe", "Manage My Paperless Billing", "Quest Locations inside Food-and-Drug Stores", "See Insurance Providers List", "Get Your Results - MyQuest™", "Top Questions", "Get MyQuest™ Mobile App", "Get Test Reminders", "FAQs", "Innovations That Matter", "Discover Easy Pay™", "Order Your Own Lab Tests - QuestDirect™", "Commit to Testing".
- Happening Now:** A photo of a woman looking at a tablet, with text below: "See your test results whenever and wherever", "Access the MyQuest™ by Care360 patient portal and mobile health app."

OPTION 2-QUEST: SPECIMEN COLLECTION AT THE CHD

- If CHDs would like to collect patient specimens themselves to submit to QUEST follow these instructions:
 - Zika Virus RNA, Qualitative, Real-Time RT-PCR Panel, Serum/Urine, Test Code 94221(X)
 - Zika Virus Antibody (IgM), MAC-ELISA, Test Code 94264(X)
- To ensure a smooth process, consider contacting your Quest Diagnostics sales representative at 1.866.MYQUEST (1.866.697.8378) to help answer any questions you may have.

1. Collect **THREE** specimens: Serum and Urine for PCR testing and Serum for IgM testing

- Urine and serum must be submitted together and collected on the same day. If only one sample is submitted, Quest Diagnostics will not perform the test.

Specimen 1: Urine

- Preferred volume, 3.0mL. Minimum volume, 0.6mL.
- Urine should be collected in a sterile container without additives.
- Urine should always be collected with a patient-matched serum specimen.
- Immediately refrigerate.
- Urine should be transferred to a sterile tube with a secure closure to prevent leakage in transport.

- a. Label tube as urine. Label with patient name, and DOB.
- b. Place sample/tube in its **own biohazard Ziploc** bag. Include a paper towel or equivalent to absorb any leaking fluid.



Use BD vacutainer urine collection tube, BD #364979, Fisher Scientific catalog #14-375-138

Collect in urine cup and **transfer to a sterile tube** for shipping.

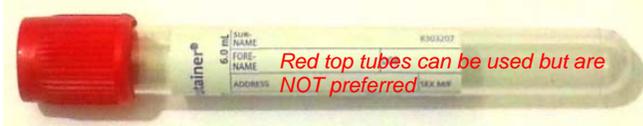
Do not submit urine in urine collection cups; they leak during transport.

Specimens 2 AND 3: Serum

- Collect **two** serum specimens, one for PCR testing and one for IgM testing.
- Preferred volume for each specimen, 3.0mL. Minimum volume for each specimen, 1.0mL
- Collect blood in a serum separator Vacutainer tube (SST) (tiger top), the preferred method, or a standard red-top tube.
- Allow blood to clot at room temperature.
- **The blood collection tube should be centrifuged as soon as possible and the serum transferred to a plastic tube, in order to avoid hemolysis. If collected in an SST and centrifuged but not transferred, Quest Diagnostics will still accept the sample.**
- Immediately refrigerate.

- o **Note: Serum received in a frozen SST or frozen standard red-top will not be accepted.**

- Label tube as serum. Label with patient name and DOB
- Spin before sending



- Place sample/tube in its **own biohazard Ziploc bag**. Include a paper towel or equivalent to absorb any leaking fluid.
- Refrigerate and call to schedule specimen pick up.*

2. Mark all three samples as Irreplaceable Specimens and follow Irreplaceable Specimen procedures below

- Place the printed completed HMS ELO order form inside the purple Irreplaceable Specimen bag (Irreplaceable bag product # 170704) along with the labeled specimens and apply a Zika label (product # 195297) to the bag.
- Immediately refrigerate.



<p>Zika Virus RNA, Qualitative Real-Time RT-PCR Panel, Serum/Urine (test code 94221) SST tube – product # 193262 Irreplaceable bag – product # 170704 Sterile container – product # 170551</p> <p>Zika Virus Antibody (IgM), MAC-ELISA (test code 94264) SST tube – product # 193262 Irreplaceable bag – product # 170704</p>
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- Specimens must not be left in lockboxes. Call for specimen pickup at 1.866.MYQUEST (1.866.697.8378). Please ensure sample is refrigerated. Please see below for stability requirements:**

Specimen Stability for PCR serum/urine:

- Room temperature: Unacceptable
- Refrigerated: 7 days
- Frozen: Unacceptable

Specimen Stability for IgM:

- Room temperature: Unacceptable
- Refrigerated: 48 hours
- Frozen: 30 days

- In special circumstances, lockbox pick up may be approved by Quest Diagnostics. Only if lockbox pickup is advised by Quest Diagnostics dispatcher, please use the CardioIQ™ bag for extended stability. Place the specimen in a pre-frozen CardioIQ bag (product number 177568). The bags must be frozen for 12 hours in advance to sustain the appropriate temperature conditions. Do not freeze the serum or urine.

- Orders must be placed in HMS.** See V. HMS Guidance for Zika Test Ordering. ELO is required when the CHD is serving as the provider and ordering testing from **QUEST**.

- a. **Place the printed completed HMS ELO order form inside the specimen shipping box along with the labeled specimens.**
- b. Order both ZIKV PCR and ZIKV IgM antibody.
- c. QUEST test numbers: Zika Virus RNA, Qualitative, Real-Time RT-PCR Panel, Serum/Urine, Test Code 94221(X); Zika Virus Antibody (IgM), MAC-ELISA, Test Code 94264(X)
- d. Use the CHD QUEST account number.

Comments:

- **PCR positives at QUEST will be sent to BPHL. Positive specimens will be automatically forwarded by QUEST to BPHL for testing.** CHDs should also coordinate submitting a DH 1847 form to BPHL for any positive samples and note as high priority for pregnant women or suspected local cases. Include standard information including pregnancy status, travel history and symptoms. **Testing will not occur unless a DH1847 form is submitted.**
- IgM positives at QUEST will be sent by QUEST to BPHL for PRNT. (BPHL will also repeat the IgM at the time of PRNT testing.)

v. HMS Guidance for Ordering Zika testing

- Zika tests for both the BPHL and QUEST should be ordered through HMS. Include your fully completed printed HMS electronic laboratory order requisition along with the specimen when sending to the laboratories for testing.

Detailed instructions on how to order in HMS can be found in the document “HMS Guidance for CHDs for Ordering Zika Testing for Pregnant Women.”

https://floridahealth.sharepoint.com/sites/INFORMATIONTECHNOLOGY/CLINIC/HMSTraining/Documents/HMSZika_GuidanceInstructions.pdf

At the time of test order or CHD notification, persons meeting PUI criteria should be entered into Merlin regardless of the location where the testing will be performed (physician private sector testing; BPHL or by the CHD under the DOH LabCorp contract for those unable to obtain testing in the private sector).

- Additional guidance for entering PUIs in Merlin can be found in Zika Virus Infection: Reporting Guidance for CHDs http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/_documents/zika-reporting-guidelines-chd.pdf

CHD Algorithm A: Algorithm for determining *where to submit specimens* from pregnant women for testing when the CHD is serving as the provider

**PREGNANT WOMAN
CHD is the provider**

For residents of counties other than Miami-Dade

A) Lives in or traveled to an area with active Zika transmission (at any point in pregnancy)

- Outside the US (e.g. Zika impacted country, Puerto Rico, US Virgin Is.);

OR

- Other areas of *current* active, local transmission **should those be declared**

B) Had sex with a partner who lives in or traveled to an area with active Zika transmission (at any point in pregnancy)

- Outside the US (e.g., Zika impacted country, Puerto Rico, US Virgin Is.);

OR

- Other areas of *current* active, local transmission **should those be declared.**

C) Suspected potential local transmission *outside* of Miami-Dade County

- Two or more** of the four symptoms: rash, fever, joint pain/arthritis, red eyes/ conjunctivitis;

AND

- Appropriate mosquito bite exposure

D) Travel to or live in

- Miami-Dade County**
<https://www.cdc.gov/zika/intheus/florida-update.html>

OR

- Brownsville, Texas**
<https://www.cdc.gov/zika/intheus/texas-update.html>

E) Does not fall into DOH identified risk category (i.e. categories A, B, C, D)

Residents of Miami-Dade County with travel to a Zika impacted country or territory;

OR

Travel to or live in Miami-Dade County or Brownsville, TX

AND

No symptoms

Has at least one of the four symptoms

- Rash
- Fever
- Joint pain/arthritis
- Red eyes/ conjunctivitis

Submit specimens to BPHL

- Place order in HMS **AND** for PUIs use Zika specific DH 1847 with pregnancy status, symptoms, travel history
- Order both ZIKV PCR (1537 Arbo Zika RT-PCR) and ZIKV IgM antibody (1539 Arbo Zika IgM ELISA)
- Enter as a Person Under Investigation (PUI) into Merlin
 - **If using the DH 1847, put the Merlin # on the DH 1847 (or provide Merlin # to submitter)** to indicate specimen approval by the CHD epidemiology program

Submit specimens to **QUEST**

- Use **electronic laboratory ordering (ELO) in HMS**
- Print HMS laboratory order/requisition form and place into shipping container with specimen
- **Zika Virus RNA, Qualitative, Real-Time RT-PCR Panel, Serum/Urine, Test Code 94221(X); Zika Virus Antibody (IgM), MAC-ELISA, Test Code 94264(X)**
- BOTH urine and serum must be sent to QUEST in the same shipment
- Call at **1.866.MYQUEST (1.866.697.8378)** to arrange pick up services
- Visit QuestDiagnostics.com/Appointment to find a patient service center