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

Version 3.0 (September 16, 2016) Green text indicates revisions

DOH: www.flhealth.gov/zika
CDC: www.cdc.gov/zika/

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**Summary**

- To ensure disease reporting and a prompt mosquito control response, health care professionals should notify their County Health Department (CHD) when Zika testing is ordered from a commercial laboratory per Florida Administrative Code, Chapter 64D-3.
- A Person Under Investigation (PUI) record should be created in Merlin for all individuals being tested who meet DOH and CDC guidance for testing. (PUI and case information is used to assess CHD patient load and appropriate corresponding funding allocations.)
- Providers should use the Florida Department of Health (DOH) and Centers for Disease Control and Prevention (CDC) guidance in deciding *who* should be tested for Zika.
- Providers should order Zika tests through *commercial labs* as they would order any other tests for their patients.
  - Providers do not need to contact the CHD to receive approval for testing in the commercial sector.
- For those who cannot obtain testing through a commercial laboratory, such as those that are uninsured or underinsured, CHDs offer testing for individuals who meet DOH and CDC guidance.
  - If a pregnant woman needs testing or insists on testing (even if she doesn't fall into the DOH and CDC guidance for testing) and cannot get it through a provider at a commercial laboratory, the pregnant woman can be tested at the CHD.
    - 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.

1. Assess for possible Zika virus exposure and evaluate for signs and symptoms of Zika virus disease.
   - Detailed testing guidance and algorithm is available at: http://www.cdc.gov/mmwr/volumes/65/wr/mm6529e1.htm?s_cid=mm6529e1_e
2. DOH guidance on testing pregnant women who live in or travel to areas of local active Zika virus transmission (currently, the limited areas of Wynwood and Miami Beach in Miami-Dade County)
   - Maps: http://www.cdc.gov/zika/intheus/florida-update.html
   - Guidance is available in the August 19, 2016 CDC Health Advisory (CDCHAN-00394): http://www.emergency.cdc.gov/han/han00394.asp
3. *If a provider suspects local transmission*, the specimens should be submitted to BPHL for testing. CHD staff should consult with state Bureau of Epidemiology staff when notified of suspected local cases.

## 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.
    a. False positives in serology testing may be due to infection from another virus that is in the same family as Zika (e.g., Dengue, West Nile virus) or non-specific cross-reaction. Thus, confirmatory testing by the CDC may be required and can take many weeks.
    b. False negatives for PCR may be due to collecting the specimen after the relatively short window of viremia (e.g., < 2 weeks). Similarly, there is a window of detecting IgM antibodies and false negatives may occur due to collecting the specimen before or after that timeframe. Individual variation may also cause false negative testing.
    c. For details on interpretation of Zika virus antibody test results, see: http://www.cdc.gov/mmwr/volumes/65/wr/mm6521e1.htm
2. 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.
3. 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 testing, 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 to be tested 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 and in the past 6 months (whichever is longer). 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 the
        - Wynwood area of Miami since June 15
        - Miami Beach area since July 14, and
        - Other areas of 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) 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.)

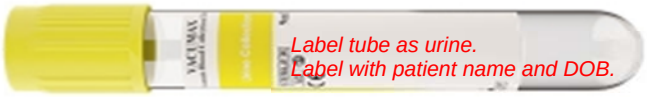
## IV. Specimen collection

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

- **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.

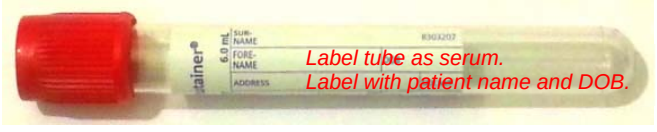




Use BD vacutainer urine collection tube, BD #364979, Fisher Scientific catalog #14-375-138

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.**

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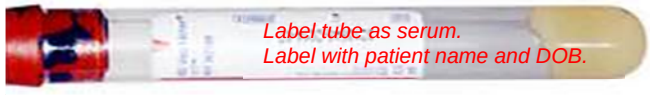


3. **Place both separately bagged specimens into a 95kPA pressure compliant bag** or other pressure compliant container.
4. **Ship specimens on cold packs.** Refrigerate do NOT freeze. Specimens should be shipped upright. **Ensure shipments will be received during the week M-F unless special arrangements 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.

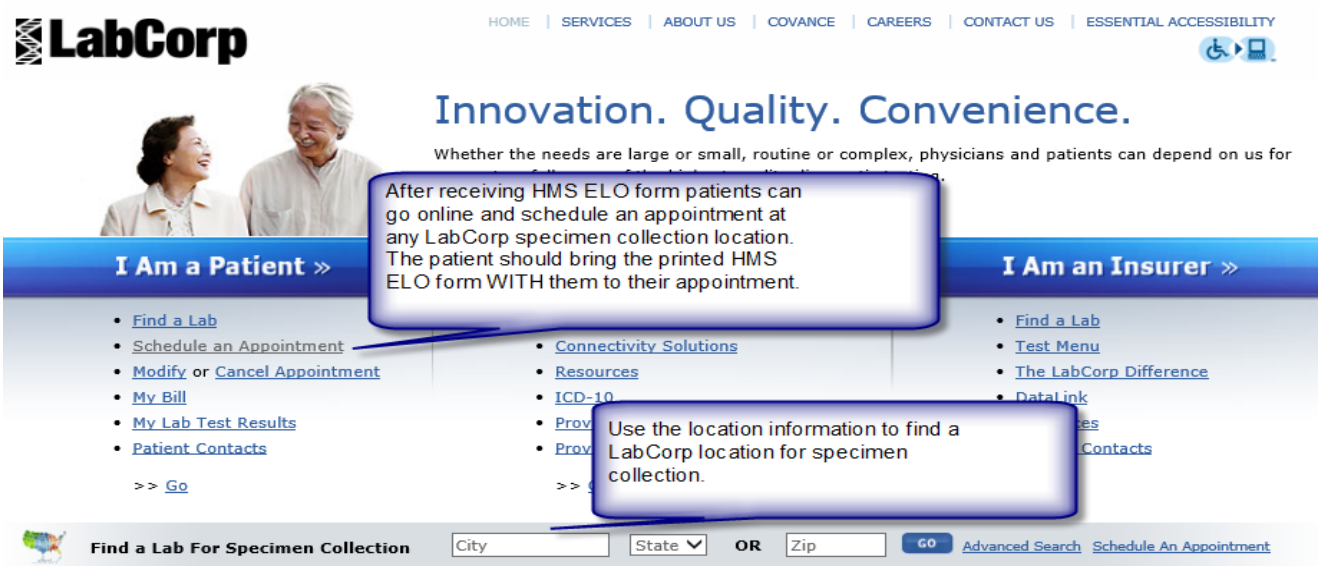

- Place the printed completed HMS electronic laboratory order form AND completed Zika specific DH 1847 inside the specimen shipping box. Submit one DH 1847.
  - Order both ZIKV PCR and ZIKV IgM antibody
  - BPHL test numbers: 1537 Arbo Zika RT-PCR 1539 Arbo Zika IgM ELISA


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 - LabCorp** (three options)

**OPTION 1-LabCorp:** SPECIMEN COLLECTION AT A LABCORP LOCATION. Preferred.

- CHDs have the option to send patients to a LabCorp location for specimen collection. This option is suggested as preferred to ensure LabCorp specimen collection and shipping requirements are met. To ensure a smooth process, consider contacting your local LabCorp 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.
  1. Evaluate patient and collect screening questions.
  2. Complete LabCorp 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.
        - LabCorp test numbers: Zika Virus NAA Comprehensive (139600); Zika Virus MAC-ELISA (163049)
     b. Print HMS specimen requisition form.
     c. Provide printed specimen requisition form to patient. The patient MUST take the printed requisition form WITH them to LabCorp at the time of their visit.
     d. Instruct patient to go to a LabCorp specimen collection locations.
        - Visit www.LabCorp.com to find specimen collection locations.
        - A patient can go to any LabCorp location.
        - A patient can go on line to schedule an appointment at a LabCorp facility AFTER they have their printed HMS ELO order from.
        - Patients can also go to a LabCorp location without scheduling an appointment. Walk-in wait times will apply.



**OPTION 2-LabCorp:** SPECIMEN COLLECTION AT THE CHD, (LabCorp no longer requires urine specimens to be submitted frozen.)

- **Collect BOTH specimens: Urine and Serum**
  - **Urine and serum must be submitted together and collected on the same day; if only one specimen is submitted, LabCorp will reject it and NO testing will be completed.**

**Specimen 1: Urine** specimen (1-3ml).

- 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.
  c. *REFRIGERATE.* LabCorp now accepts refrigerated urine; it no longer has to be submitted frozen. Due to additional efforts to prepare FROZEN urine, refrigeration is recommended.

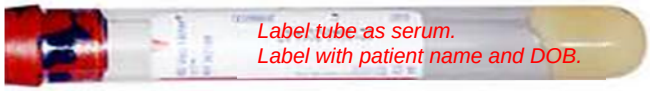


Use BD vacutainer urine collection tube, BD #364979, Fisher Scientific catalog #14-375-138

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 tiger top tube (1-2ml). RED top tubes are **not** accepted.
   a. Collect 2 serum specimens
   b. Label tube as serum. Label with patient name and DOB
   c. Spin before sending


   d. Place sample/tube in its **own biohazard Ziploc** bag. Include a paper towel or equivalent to absorb any leaking fluid.
   e. *Refrigerate and call to schedule specimen pick up.* Once samples arrive at LabCorp, serum can be refrigerated for up to 7 days from collection date and be used for PCR testing and held up to 14 days for IgM antibody testing.
   f. Due to additional efforts to prepare FROZEN serum, refrigeration is recommended.
      - **Under the DOH-LabCorp contract, LabCorp accepts refrigerated serum and urine.** This arrangement is specific to DOH at this time. Non-DOH providers must submit FROZEN serum and urine.
      - FREEZE if specimen pick up cannot occur within the same or next day.

- If freezing, serum must be aliquoted into a clean, sterile container (without separation gel or preservatives) and FROZEN until shipped. **Do not freeze in the same tube that has the red blood cell component.**

3. **Shipping to LabCorp:**
   a. Call LabCorp 1-800-788-3818 to arrange pick up services with LabCorp. Do NOT package and ship directly to LabCorp.
   b. LabCorp now accepts refrigerated urine specimens at this time. Both serum and urine can now be submitted refrigerated (recommended) or frozen.
   c. **Both specimens (serum and urine) must be submitted at the same time**.
4. **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 LabCorp.
   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. LabCorp test numbers: Zika Virus NAA Comprehensive (139600); Zika Virus MAC-ELISA (163049)
   d. Use the CHD LabCorp account number but do not pay any bills related to this testing. Central Office will pay the charges.

Comments:

- **PCR positives at LabCorp will be sent to BPHL at the request of the CHD. Positive specimens will no longer be automatically forwarded.** Specimens will be held at LabCorp for 30 days following the result being available. All positive specimens will no longer be automatically forwarded by LabCorp 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 LabCorp will be sent by LabCorp to CDC for PRNT.
  - The process for receiving these results is in process.

## V. HMS Guidance for Ordering Zika testing

- Zika tests for both the BPHL and LabCorp 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." http://www.floridahealth.gov/diseases-and-conditions/zika-virus/_documents/hms-zika-guidance-instructions.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**

**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
- ☐ Miami Beach (after July 14);
- ☐ Wynwood (after June 15) impacted area in Miami;
- ☐ Other areas of local transmission if declared

**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
- ☐ Miami Beach (after July 14);
- ☐ Wynwood (after June 15) impacted area in Miami;
- ☐ Other areas of local transmission if declared

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

- ☐ **Two or more** of the four symptoms: rash, fever, joint pain/arthralgia, red eyes/ conjunctivitis;
  AND
- ☐ Appropriate mosquito bite exposure

**Travel to or live in Miami-Dade County** (at any point in pregnancy) ***BUT NOT TO*** the Miami Beach, Wynwood area of active transmission (or other areas of local transmission if declared)

**Requests testing but *does not* fall into DOH or CDC identified risk category;** such as asymptomatic or travel to Miami-County outside of active transmission areas or no travel or sexual exposures

**Has *at least one* of the four symptoms**

- ☐ Rash
- ☐ Fever
- ☐ Joint pain/arthralgia
- ☐ 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
  - o **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 **LabCorp**

- **Use electronic laboratory ordering (ELO) in HMS**
- Print HMS laboratory order/requisition form and place into shipping container with specimen
- Zika Virus NAA Comprehensive (139600); Zika Virus MAC-ELISA (163049)
- BOTH urine and serum must be sent to LabCorp in the same shipment
- Urine must be submitted FROZEN (at this time)
- Call 1800-788-3818 to arrange pick up services with LabCorp
- Visit www.LabCorp.com to find a specimen collection location