Zika Testing Approval Process Guidelines

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Please note: this document and associated forms and reference documents are subject to change, as Zika is an emerging infection in the Americas. Changes to the forms and reference materials will be communicated via SCDP listserv or the Health Alert Network as they occur. State and local public health personnel in Missouri are encouraged to routinely consult the most up-to-date information provided on the Centers for Disease Control and Prevention (CDC) Zika virus page at http://www.cdc.gov/zika/index.html.

Purpose: The purpose of this document is to provide guidance for staff of Missouri Local Public Health Agencies (LPHAs) that opt to screen requests and provide preliminary approval to medical providers for Zika virus testing (hereafter, testing). Please note, the decision to conduct the screening and provide preliminary approval is up to each LPHA and is not a requirement. Final approval for testing must be given by Missouri Department of Health and Senior Services (DHSS) staff prior to a medical provider submitting specimens to the Missouri State Public Health Laboratory (SPHL). CDC currently conducts confirmatory Zika testing, when needed, for specimens submitted to the SPHL and requires state facilitation of test requests originating within the states’ jurisdictions. Links to the required forms and various reference documents are provided. Descriptions of these documents can be found following the Patient Results and Investigation section of this document.

Test requests will only be accepted from and subsequent preliminary and final approval granted to health care providers or their designee, such as medical laboratories. Members of the public that request testing from a LPHA or DHSS are recommended to consult a medical provider.

Testing Approval Process with LPHA Providing the Screening and Preliminary Approval

LPHAs may choose to work with medical providers within their jurisdiction to screen requests and provide preliminary approval for testing. This section outlines the procedure for LPHAs to conduct the screening and preliminary approval process.

For Calls Received During Regular Business Hours

1) Obtain the information needed to screen the patient from the medical provider. LPHA staff fills out the Zika Virus Specimen Submission Screening Form to ensure pertinent information is obtained and is accurate. (Note: please do not send the screening form to the medical provider for completion).

2) If preliminary approval is granted by the LPHA, inform the provider that you will follow-up with DHSS immediately for final approval and to coordinate the testing. In addition, let the medical provider know you will call back promptly with the final decision and to provide additional guidance.

3) Contact DHSS, Bureau of Communicable Disease Control (BCDCP) main number (573)751-6113 to request consultation with a BCDCP Epidemiologist. Note: please let the DHSS staff answering
the phone know which LPHA you are with and that you are requesting approval for Zika testing. Please call the main BCDCP number to request final approval, which will help to ensure an epidemiologist is immediately available for consultation and approval. This will in turn help to provide a prompt response back to the medical provider. The DHSS staff member will review the patient travel and symptom history with the LPHA staff member, and then provide approval for testing, if appropriate. Based on the patient’s symptom onset date, the DHSS staff member will determine the specimen type (urine and serum, or serum alone) needed for testing.

4) The LPHA staff member will notify the medical provider of the outcome of the final approval request immediately.

5) If testing is approved, the LPHA will fax or email the provider both the Physician Instructions for Completing Zika Test Request Forms and Specimen Packaging/Transportation Instructions. Note: Please be prepared to answer the provider’s questions about specimen collection and completion of the Virology Test Request Form for the Missouri State Public Health Laboratory and CDC Specimen Submission Form 50.34 and provide guidance for specimen packaging and transportation. The LPHA will likely need to provide this guidance to the medical provider and/or medical laboratory to ensure the required forms are completed and submitted with satisfactory specimens. In addition, inform the provider of results reporting process, as outlined in the Patient Results and Investigation section of this document.

Before hanging up with the medical provider, it is very important that the LPHA also provides the Patient Information Sheet to the medical provider and stresses the importance that it is passed on to the patient. It may take several weeks to get final results back, which may be too late for the patient to implement some of the stated control measures.

6) After the provider’s questions have been answered and specimens are being submitted, the LPHA sends the Zika Virus Specimen Submission Screening Form via fax or secure email to the approving DHSS staff member. DHSS staff will ensure the information is communicated to the SPHL and is entered into WebSurv. Please notify the approving DHSS staff member in the event specimens were approved, but no specimen is being submitted. Note: specimens received at the SPHL will only be tested if a Zika Virus Specimen Submission Screening Form submitted by a DHSS staff member is on file at the SPHL.

7) If testing approval is not granted by DHSS, the DHSS staff member will provide a verbal explanation in addition to a follow up written response to the LPHA staff member stating the reason(s) via email. Examples include:

- Patient travel history does not include countries determined by CDC to have ongoing Zika transmission.
- Patient is not pregnant and does not have symptoms of Zika virus infection.
- Patient does not have relevant sexual exposure to a person with Zika virus infection.
Note: please let the approving DHSS staff member know if you disagree with the decision not to test and explain the reasons why testing should be conducted. This will help facilitate additional discussion and consultation as needed.

Testing Approval Process with LPHA Referral to DHSS

Some LPHAs may choose to refer providers directly to DHSS for testing approval. This section outlines the procedure to be followed in this instance.

1) The LPHA receives a request from a provider requesting testing for a patient and either transfers the provider to or provides the phone number for BCDCP (573-751-6113).

2) The provider will be transferred to the first available DHSS staff member to carry out the approval process, provide patient prevention information, and help the provider prepare the specimen submission forms as outlined above.

3) The DHSS staff member will provide a written response to the LPHA to notify of the outcome of the provider call via email. Examples include:

- Thank you for referring (Provider’s name) for Zika virus testing approval. The patient has been approved for testing.
- Thank you for referring (Provider’s name) for Zika virus testing approval. The patient was not approved for testing, as he did not fit required travel and/or symptom history.

For Calls Received After Regular Business Hours, Weekends, or Holidays

1) For LPHAs conducting the screening and preliminary process: contact the DHSS Emergency Response Center (ERC) at 800/392-0272. Note: please let the ERC staff answering the phone know which LPHA you are with and that you need to request approval for Zika testing. A DHSS staff member will call you back promptly. The same process as described above will be followed. Additional guidance will be provided regarding specimen collection, storage, and shipping as needed.

2) For LPHAs referring provider directly to DHSS: request the provider contact the DHSS ERC at 800/392-0272 for consultation and approval.

Patient Results

When Zika laboratory results are received from CDC, the SPHL will notify the submitter listed on the test request forms, of both the positive and negative results via phone call. The DHSS, Bureau of Reportable Disease Informatics (BRDI) will enter all laboratory results into WebSurv, which will then be immediately accessible to LPHAs. BCDCP District Epidemiologists will continue to notify LPHAs of results received from individuals from their jurisdiction.
For those medical providers with patient care questions, general guidance is available at http://www.cdc.gov/zika/hc-providers/index.html. For additional questions, please reach out to the District Epidemiologist contact in your area.

**Required Forms for Testing**

*To be completed by:* LPHA staff providing preliminary approval for testing OR DHSS staff in the event the LPHA refers a requesting provider for testing approval

1) **Zika Virus Specimen Submission Screening Form**
   This form is used to guide the testing screening and approval process and to provide information for Websurv entry. Once completed, this form will be promptly submitted by a BCDCP epidemiologist to the SPHL indicating that the specimen is approved for testing.

*To be completed and submitted by:* Requesting provider once final approval is received from DHSS.

2) **Virology Test Request Form for the Missouri State Public Health Laboratory**
   This form is used to request testing for a specimen submitted to the SPHL. It must be completed and submitted with the specimen to the SPHL. Note: specimens received at the SPHL will only be tested if a Zika Virus Specimen Submission Screening Form submitted by BCDCP is on file at the SPHL.

3) **CDC Specimen Submission Form 50.34**
   This form is used to request testing of specimens submitted to the CDC. When needed, confirmatory testing is currently done at CDC, but specimens must be submitted in coordination with the SPHL. This form must be submitted with the specimen to the SPHL. Note: specimens received at the SPHL will only be sent to CDC for testing if a Zika Virus Specimen Submission Screening Form submitted by DHSS staff member is on file at the SPHL.

**Case Investigation**

Zika case investigations can be challenging given the intricacies of laboratory testing and diagnosis; the various modes of transmission; risks of infection during pregnancy; environmental assessment and mitigation; etc. Individual cases and the subsequent case investigation and response activities may vary on a case by case basis. As stated, Zika presents many challenges and recommendations continue to change as the outbreak expands and more is learned about the disease.

The primary concerns of Zika are the risks of birth defects associated with contracting the virus during pregnancy and the potential for local mosquitos to become infected resulting in local transmission of the disease. Zika cases should be investigated promptly to address the following questions and concerns:

- Exposure: How did the case contract Zika (travel, sex, blood products, local mosquitos)?
- Transmission: What are the possible risks of transmission to others (expectant mother to fetus, sex, donation of blood products) and to the local mosquitos?
• Environmental Assessment: Are there concerns for increased mosquito breeding sites or other risk factors in the immediate environment that require possible mitigation?
• Surveillance for local transmission: Did any household or close contacts of a case develop symptoms of Zika?

The specific steps required to investigate cases of Zika may vary from case to case. To identify and address the stated concerns, a Zika case investigation may include completion of the following steps:

☐ Notification of results: Confirm the positive results have been communicated to the medical provider and that the provider has notified the patient.
☐ Case interview: Completion of the DHSS Interim Zika Case Report Form
☐ Case education: Provide the case specific recommendations, including but not limited to:
  ▪ Avoid mosquito bites while viremic
  ▪ Prevent sexual transmission
  ▪ Information regarding conception and blood donation
☐ Environmental assessment and mitigation activities related to mosquito control
☐ If pregnant or recently delivered, complete the U.S. Zika Pregnancy Registry case report forms
☐ Notification and education of reported sexual contacts
☐ Enhance surveillance:
  ▪ Advise the case to report any household or close contacts that develop symptoms of Zika.
  ▪ Conduct a follow up call with the case 21 days after onset to verify no household or contacts developed symptoms of Zika.

Zika Case Investigation Forms (will be provided in the event of a case being identified in your jurisdiction):
• DHSS Interim Zika Case Report Form
• DHSS Zika Investigation Summary
• CDC Zika Pregnancy Registry Forms: Maternal Health History; Neonate Assessment; Infant Follow Up (2, 6, and 12 months); Laboratory Results; Supplemental Imaging and Diagnostics

DHSS Staff are available to assist with the follow up investigation of Zika. Please contact the BCDCP District Epidemiology Specialists in your District for assistance with case investigation and the Office of Veterinary Public Health for assistance with the environmental assessment and mitigation.
Reference Documents

1) Zika Virus Screening Algorithm for Initial Testing
   This document is a flow chart to facilitate the testing approval decision. The algorithm is used for public health decision making and is not to be distributed.

2) Physician Instructions for Completing Zika Test Request Forms and Specimen Packaging/Transportation Instructions
   This document is a reference for physicians to use while completing required specimen submission forms. It should only be provided to physicians with one or more patients that have been approved for testing by LPHA staff (preliminary approval) or DHSS staff (final approval).

3) Patient Information Sheet
   This document provides basic prevention information for patients at risk for Zika virus infection. Titled *Infection Prevention and You: what you need to know about Zika virus*, it is provided with permission from the Association for Professionals in Infection Control and Epidemiology.