Health Update

KITSAP PUBLIC HEALTH DISTRICT

May 3, 2016

New commercially available PCR testing for Zika virus; antibody testing still via CDC/Local Health

Actions Requested

- **Be aware that some commercial labs may start offering RT-PCR testing for Zika virus as early as this week.**
  - Antibody testing is still limited to CDC and certain public health labs (see below).
- **Understand the timeframes and patients for which RT-PCR versus antibody testing is appropriate, as well as the interpretation of negative results and need for further testing:**
  - RT-PCR should only be ordered if a patient is exhibiting clinical signs/symptoms consistent with Zika virus infection, *and* the specimen was collected within 7 days of illness onset.
    - Positive RT-PCR results are indicative of current infection.
    - Negative RT-PCR result on a specimen collected >=4 days after illness onset *does not rule out* infection. A specimen should be obtained for ELISA IgM testing at CDC (with approval).
  - RT-PCR testing is *not* indicated for asymptomatic individuals, including asymptomatic pregnant women.
    - Negative RT-PCR result on an asymptomatic person *does not rule out* infection.
  - ELISA IgM testing should be performed for patients whose illness onset was >7 days prior to specimen collection and for asymptomatic pregnant women.
    - Approval for antibody testing at CDC is still required prior to submission. (See below).
- **Use attached screening form to help identify if Zika testing is warranted.**
- **Consider ordering additional testing for dengue and chikungunya simultaneously** if the patient is exhibiting clinical signs/symptoms consistent with Zika or other arboviral infections, given the clinical similarity and cross-reactivity. Both of these tests are available via commercial labs.
- **Report any suspect Zika virus cases and request antibody testing by calling us.** Prior to collecting specimens, please call our office. Have travel/exposure history and clinical information details ready to discuss.

For questions, please contact our Communicable Disease staff at 360-337-5235.

Background

On April 28, the Food and Drug Administration (FDA) granted an Emergency Use Authorization to Focus/Quest Diagnostics for the use of a Zika virus RNA Qualitative Real-Time reverse transcriptase polymerase chain reaction (RT-PCR) test. Quest Diagnostics announced that it will begin offering testing as early as this week. This is the first Zika virus test to be offered by a commercial laboratory. At this point, RT-PCR is the only test that will be offered commercially; antibody testing by ELISA IgM is still only available at CDC and certain public health labs.

Resources

(1) CDC Zika virus website for healthcare providers: www.cdc.gov/zika/hc-providers/index.html
(2) Previous Zika virus health alerts: www.kitsappublichealth.org/healthcare
(3) FDA announcement of EUA for Zika virus RT-PCR test: www.fda.gov/downloads/medicaldevices/safety/emergencysituations/ucm498274.pdf

Attachments: (1) KPHD screening checklist and request form for Zika virus testing at CDC

Guidance for Providers Regarding Evaluation and Testing of Persons with Probable Exposure to Zika virus

April 29, 2016

Criteria for testing: person must meet any one of the following criteria:

** Check the CDC web site for current risk areas: (http://www.cdc.gov/zika/geo/)*

#	Criteria	Yes	No
1	**Any person** (male or female) **with illness consistent with Zika virus disease, including at least two of: acute onset of fever, maculopapular rash, arthralgia, or conjunctivitis,** occurring EITHER: a) during or within 2 weeks of last travel date to a risk area*; **OR** b) during or within 2 weeks of unprotected sex with a man who has tested positive for Zika virus *or* who traveled to a risk area* and had symptoms of Zika virus disease during his travel or within 2 weeks of his return → Ideally obtain serum within the first week of illness (if possible)		
2	**Symptomatic pregnant women with at least 1 symptom** (acute onset of fever, maculopapular rash, arthralgia, or conjunctivitis) after unprotected sex with a man with possible Zika virus exposure.		
3	**Asymptomatic pregnant women** who EITHER: a) traveled while pregnant to a risk area*; **OR** b) had unprotected sex with a man who has tested positive for Zika virus or who traveled to a risk area* and showed Zika symptoms during travel or within 2 weeks of his return; **OR** c) had possible exposure (sexual^ or travel) in the 8 weeks before conception (6 wks before LMP) → Collect serum 2-12 weeks after return/exposure *^Testing is not currently recommended if both partners are asymptomatic.* *NOTE: If fetal ultrasounds detect microcephaly or intracranial calcifications, pregnant women who originally tested negative for Zika virus infection or who were not tested following travel should be retested.*		
4	**Woman experiencing fetal loss** with travel to a risk area during pregnancy if not previously tested.		
5	**Infants** born to women with travel to risk area during pregnancy with EITHER: a) maternal positive or inconclusive test result for Zika virus; **OR** b) infant microcephaly¥ or intracranial calcifications; **OR** c) acute symptoms of Zika disease (see #1 above) in the infant within 2 weeks of birth and mother traveled to a risk area* within 2 weeks of delivery *¥ For possible congenital Zika, microcephaly is defined as occipitofrontal circumference <3rd percentile, based on standard charts for sex, age, and gestational age at birth. If circumference is ≥3rd percentile but notably disproportionate to body length, or if CNS deficits exist, further evaluation for Zika infection might be considered.*		

NOTE: Our Communicable Disease staff at Kitsap Public Health District are available for consultation as needed. Call us at (360)-337-5235.

→ **See page 2 for Laboratory Testing guidance**

Laboratory Testing for Zika Virus

- Patients with Zika virus disease symptoms should generally also be evaluated for dengue and/or chikungunya because of strong cross-reactivity and clinical similarity. Consider ordering these tests simultaneously via commercial lab. If dengue infection is possible, advise the patient to avoid aspirin and NSAIDs.
- **Limited Zika virus testing (RT-PCR) is now being offered commercially, with more extensive testing at CDC.**
- **Timeframes and patients for which RT-PCR versus IgM antibody testing is appropriate:**

Patient Symptomatic	Specimen Collection Timing	Test	Comments	Pre-Approval Required
Yes	Within 7 days of illness onset	RT-PCR	• Positive RT-PCR results are indicative of current infection. • Negative RT-PCR result on a specimen collected >=4 days after illness onset *does not rule out* infection. A specimen should be obtained for ELISA IgM testing at CDC (*with approval*). • *Not* indicated for asymptomatic individuals. Negative result on an asymptomatic person *does not rule out* infection.	No; commercially available
Yes	>7 days after illness onset	IgM ELISA		Yes; offered at CDC
No	Ideally 2-12 weeks after exposure	IgM ELISA	Interpretation is complex in asymptomatic persons. While a negative IgM obtained 2-12 weeks after exposure would suggest a recent infection did not occur, it does not definitively rule out infection.	Yes; offered at CDC

- **For CDC testing: Submissions must still be pre-approved.**
    - In Kitsap County, please call the Kitsap Public Health District (KPHD) at (360)-337-5235 to request testing prior to collecting specimens.
    - Serum (0.25 mL minimum, 2 mL preferred) spun down in a red or tiger top (serum separator) tube and frozen to -70^{o}C (unless for a perinatal case – see below).
    - For perinatal cases collect maternal serum **and** as many of the following as applicable and available: amniotic fluid, fixed placenta and umbilical cord tissue, frozen placental tissue and umbilical cord tissue, umbilical cord serum or infant serum (0.25 mL) within 2 days of birth. For still births, contact KPHD.
    - All specimens require two patient identifiers, both on the specimen label and the submission form
    - **Specimen submission form**: www.doh.wa.gov/Portals/1/Documents/5230/302-017-SerVirHIV.pdf
    - Ship appropriate specimen(s) with completed submission form to WA PHL (address on form).
    - **The following intake form (page 3) MUST be completed and submitted to KPHD for approval prior to specimen submission.** Be sure to complete all fields. Missing details will result in specimen rejection. Fax completed form to our Communicable Disease confidential fax at (360) 337-5241.

Date:_____

Zika Virus Intake Form

PATIENT

Last name:_____ First name:_____

DOB: _____ Sex: ☐ Male ☐ Female County: _____

Patient Address:_____ Phone Number:_____

SUBMIT BY

Physician / Hospital / Lab / Clinic name:

_____

Contact name:_____Phone:_____

SPECIMEN

Date of Specimen Collection (*if asymptomatic pregnant woman, must be 2-12 weeks after travel*):_____

Shipping date:_____

Specimen Source: ☐ Serum ☐ Amniotic Fluid ☐ CSF ☐ Fixed tissue ☐ Frozen tissue

☐ Other:_____

EPIDEMIOLOGY

Date of Symptom Onset**:**_____ OR ☐ Asymptomatic and pregnant

Symptoms *(check all) if patient is not pregnant, must have 2*: ☐ **Fever** ☐ **Rash** ☐ **Conjunctivitis** ☐ **Arthralgia**

☐ Guillain-Barré Syndrome ☐ **Asymptomatic** ☐ Other: _____

Patient pregnant? ☐No ☐Yes, # weeks gestation currently:_____ OR estimated delivery date: _____

Fetal/infant anomalies: ☐ None ☐ Unk ☐ Microcephaly ☐ Intracranial calcifications

☐ Other: _____

Flavivirus Vaccination			
	N	Unk	If Yes/date
Yellow Fever			
Japanese Enceph.			
Tick-borne Enceph.			

Commercial Labs Ordered					
	N	Unk	If Yes/DOC	Lab	Results
CHIK PCR					
CHIK IgM/IgG					
Deng PCR					
Deng IgM/IgG					

Past Arboviral Infection			
	N	Unk	If Yes/Date
Yellow fever			
Japanese encephalitis			
Tick-borne enceph.			
St. Louis encephalitis			
West Nile virus			
Dengue			
Chikungunya			

TRAVEL HISTORY

Patient traveled to an area with Zika transmission within 14 days prior to symptom onset or within 12 weeks if asymptomatic?

□ Unk □ No □ Yes, countries/cities and dates of travel:

Infant with maternal history of travel to an area with Zika transmission?

□ N/A □ Unk □ No □ Yes, countries/cities and dates of travel:

Patient's sexual partner has history of Zika-like illness within 2 weeks of travel to an area with Zika transmission?

□ N/A □ Unk □ No □ Yes, date of symptom onset:_____AND countries /cities and dates of travel:

NOTES

Notes:

CALL KITSAP PUBLIC HEALTH AT (360) 337-5235. FAX <u>COMPLETED</u> FORM TO (360) 337-5241.