



## **TO: Physicians and other Healthcare Providers**

# Please distribute a copy of this information to each provider in your organization.

Questions regarding this information may be directed to the following Region IV health officers:

Alan Melnick, MD, MPH, CPH Clark County Public Health, (360) 397-8412

Sarah D. Present MD, MPH

Skamania County Community Health, (509) 427-3850 Wahkiakum County Health & Human Services, (360) 795-6207

Jennifer Vines, MD, MPH Cowlitz County Health & Human Services, (360) 414-5599

### **Alert categories:**

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; no immediate action necessary.

## HEALTH ADVISORY May 3, 2016

## FDA Approval for commercial Zika virus RT-PCR test



### **Summary**

The FDA has granted an Emergency Use Authorization (EUA) to Focus/Quest Diagnostics for the use of a Zika virus RNA Qualitative Real-Time 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.

http://www.fda.gov/downloads/medicaldevices/safety/emergencysituations/ucm498274.pdf

#### **Recommendations**

Please share the following information with all of your providers, including OB:

- At this point, RT-PCR is the only test that will be offered commercially. ELISA IgM testing is still only available at CDC and needs to be requested through your local health jurisdiction (LHJ).
- RT-PCR should only be ordered if (1) a patient is exhibiting clinical signs and symptoms
  consistent with Zika virus infection, AND (2) the specimen was collected within 7 days of
  illness onset.
- RT-PCR testing is NOT indicated for asymptomatic individuals, including asymptomatic pregnant women, and a negative RT-PCR result on an asymptomatic person DOES NOT RULE OUT INFECTION.
- Interpreting RT-PCR results:
  - → Positive RT-PCR results are indicative of current infection.
  - → Negative RT-PCR results on a specimen collected ≥4 days after illness onset DOES NOT RULE OUT INFECTION. If IgM testing at CDC is indicated and has been approved by your LHJ, a specimen should be sent to the Washington State Public Health Lab.
- For patients whose illness onset was >7 days prior to specimen collection or for asymptomatic pregnant women, following LHJ approval for ELISA IgM testing at CDC, specimens should continue to be sent to the Washington State Public Health Lab.
- Providers should consider ordering testing for dengue and chikungunya if the patient is exhibiting clinical signs and symptoms consistent with Zika or other arboviral infections.

### For questions or to request testing through CDC, please contact:

- Clark County Public Health: (360) 397-8182.
- Cowlitz County Health Department: (360) 414-5599
- Skamania County Community Health: (509) 427-3850
- Wahkiakum County Health and Human Services (360) 795-6207

## Thank you for your partnership.