Zika Virus Outbreak Response
National Public Health Laboratory Call
08/02/2016

Call Summary

Main Contact Emails
CDC Emergency Operations Center (EOC) Contact: eocvent278@cdc.gov
LRN Helpdesk: LRN@cdc.gov
APHL EOC Contact: eoc@aphl.org

Welcome (Kelly Wroblewski, APHL)
Overview of Laboratory Guidance (Julie Villanueva, CDC)
CDC Zika Virus webpages have been updated to provide an improved user experience including updates to the Clinical Guidance Webpages and Summary pages for Healthcare workers caring for pregnant women.

Two new MMWR reports regarding Zika have been recently published
Update: Interim Guidance for HCP Caring for Pregnant Women with Possible Zika Virus Exposure--US, July 2016


Laboratory Guidance, updated July 28, 2016
- Testing of specimens within the United States to determine possible Zika virus infection should be limited to specimens collected from patients meeting CDC’s clinical and epidemiological criteria for testing
- There are now 3 algorithms for testing: All symptomatic persons with specimens collected within 14 days, symptomatic persons with specimens collected on or after 14 days and asymptomatic pregnant women
  - For symptomatic persons: collect urine and serum within 14 days of onset of symptoms
  - If specimens collected > 14 days the first test should IgM Serology
  - For both symptomatic and asymptomatic pregnant women with specimens collected AFTER 14 days with a IgM positive serology, both urine and serum should then be tested by real-time PCR. If either are positive testing can stop, if negative, confirm positive IgM ELISA with PRNT.

Questions APHL has received so far:
Q: There have been several questions about the algorithm for testing asymptomatic pregnant women where it says to perform rRT-PCR testing for Zika virus only. Does that mean that PHLs should maintain a separate single-plex test for asymptomatic pregnant women in addition to the Trioplex?
A. No, you can use the Trioplex.

Q: Will Trioplex package insert be updated to 14 day window?
A. There have been some EasyMag manufacturing issues that have impeded CDC work on the Trioplex EUA amendment, but CDC is still working on it. The amendment would include package insert update as well.

Off label use (Stacey Spies, CDC)
Certain situations may warrant a need to use the EUA Assays off-label for investigations. Negative results in these circumstances may not be definitive negatives for Zika virus. CDC requests that they are contacted before
the EUA is used off-label. FDA has requested CDC to provide any information about the use of these tests off-label

**Commercial Testing Availability (Toby Merlin, CDC)**

HHS recognized the potential need for commercial laboratories to perform Zika virus serology so that PHL are not overwhelmed. CDC was asked to license the Zika MAC-ELISA for interested commercial laboratories and has been working for the last 2 months with Quest, LabCorp, ARUP and Mayo. Each of the mentioned laboratories has signed license agreements that permit them to perform the CDC Zika MAC-ELISA under that EUA. Part of the licensing agreement is that the assay must be performed as indicated in the EUA and per CDC guidance, marketing materials must be reviewed by CDC prior to use and it is term-limited until a commercial Zika virus serology enters the market. Positive and equivocal results will still require PRNT. The recommendation for how the PRNT will be requested is still under consideration.

Option 1: Commercial Laboratory sends directly to CDC and CDC reports result to commercial laboratory

Option 2: Commercial Laboratory works through the State PHL and they request from CDC

Both options have pros/cons and the recommendation has not yet been made.

**Blood Safety Testing (Michelle Chevalier, CDC)**

FL DOH has active local transmission. At the end of last week the FDA issued new recommendations for that area:

Statement from Peter Marks, M.D., Ph.D., Director, FDA’s Center for Biologics Evaluation and Research
Advice to Blood Collection Establishments on Non-Travel Related Cases of Zika Virus in Florida

**Recent Questions**

**Q:** How does blood safety define it's area of risk?

**A:** Unlike the mosquito vector which is very geographically limited, Infected donors are not limited to a specific area, therefore a broader area, Miami-Dade and Broward Counties, was defined for blood safety purposes.

**Q:** What testing is available for blood donation screening?

**A:** There are two IND protocols for screening the blood supply for Zika virus--Hologic/Grifols and Roche. There is also a pathogen reduction technology for plasma but not for red blood cells at this time

**Q:** Should public health laboratories be performing blood donor testing?

**A:** No, PHLs are not being asked to confirm any blood donor testing, but may choose to do parallel testing

**Q:** Are there different recommendations for testing organ donors or cadaveric specimens?

**A:** Tissue banks are advised to test tissue and organs per FDA recommendations which has provisions for testing living donors and organ transplants but not for cadaveric specimens.

**Local Transmission (Carina Blackmore; FL DOH)**

Situational Update on Local Transmission Investigation/ Testing Approaches in FL. 1/2 Miami-Dade, 1/2 Miami-Brower. Initially required for case definition: 3 of 4 symptom: rash, fever, joint pain, conjunctivitis. Now accept with 2 of 4 symptoms for testing.

- **1st individual (Miami-Dade Co):** Astute clinician saw the first patient with 3/4 symptoms with no travel history ordered testing. Testing was positive and prompted an extensive investigation: Person history, travel, sexual, potential blood-borne history (Transfusion or needle use). DIS was also called in to assist.
  - 54 close contacts tested, all negative
- **2nd individual (Broward Co):** Patient with symptoms and no travel history. Testing partners and roommates to verify mode of transmission. Likely non-travel associated cases.
- 17 close contacts, all negative
- 2 additional cases that were not linked to residency, but work site, worked 150 meters from each other.
  - Found symptomatic co-worker that was positive, and then tested others identifying 10 additional cases are all within the 150 meter radius
- A major investigation in the same area and in the local businesses was begun including collection of serum, urine and semen (when appropriate) from symptomatic works.
- Additionally a cluster survey was initiated focusing on the area where transmission was likely and they conducted thorough evaluations
- Lastly, a urine testing campaign within community (within the 150 meter radius) was performed
- All 3 lab in the state are currently testing
  - Tampa and Jacksonville: PCR and ELISA
  - Miami-Dade: Off Label testing of Urine for surveillance by PCR

**CDC Epidemiology Update(???)**
A six-member CERT team has been dispatched to FL, members have arrived or will be arriving shortly to assist FL.

**Surge Planning Reminder (Jasmine Chaitram)**
LRN and APHL had calls to address Surge Planning with all states, and specifically with the 7 high-risk areas and has worked to pair the 7 high-risk areas with other laboratories to assist.

Plan should address: 1) Practices to maximize lab capacity 2) Plans to utilize other LRN labs if needed including which LRN labs have been identified to assist. Brief reminder to complete surge plans if you have not already done so and for those in the 7 high-risk areas, a reminder to submit those plans to CDC as you are able. Contact LRN/APHL if you need assistance in developing your plan.

**Questions and Answers (Q&A)**

**Q.** What private labs have approval to perform the CDC Zika MAC-ELISA?

**A.** LabCorp and Mayo have completed their verification panels. LabCorp should be announcing testing soon but Mayo is not ready yet.

**Q.** Will those needing PRNT coordinate with CDC directly or will the state coordinate?

**A.** This has not yet been finalized. There are obviously pros and cons to both approaches and CDC is carefully considering both before making a recommendation. There is also the potential that CDC will update the recommendation for samples requiring PRNT such that potentially only those IgM positives from pregnant women or of PH significance (newly suspected outbreak, associated with blood transfusion or organ transplants).

**Q.** Are any mosquito pools being tested in FL surveillance? What is the vector control response for the area?

**A.** Yes, mosquito pools are being tested, but it is very difficult to get viral RNA from *Aedes aegypti*. The state is working to aggressively control mosquitoes, but it is difficult; requires door to door larvacide treatment. Concerns about resistance and modifying approach to introduce some other types of pesticides.

**Q.** State is interested in performing PRNT, how would it need to be reported?
A. LRN results messenger is not set up to accept PRNT results. Reporting would need to be through ArboNET and to the submitter.

Q: Based on the updated interim guidance for caring for pregnant women, should pregnant women with potential sexual exposure from an asymptomatic partner with relevant travel history be tested for Zika Virus?

A: The previous recommendations did require the partner to have symptoms, but due to updated information, we know that asymptomatic persons can sexually transmit the virus. Therefore all pregnant women should be assessed for potential exposure at EVERY prenatal visit and should be tested if their sexual partner has had travel history in an area with local transmission of Zika virus.

Q: Will there be updated maps, specifically for Mexico, with actual areas of local transmission rather than the entire state as it creates a huge testing burden on states such as TX, CA, AZ and NM.

A: CDC will need to follow-up on this item.