Clinical and Public Health Laboratory Preparedness and Response

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Role of Public Health Labs in Preparedness and Response

• PHLs are at the forefront when it comes to protecting the public's health, by identifying novel / emerging threats including responding to biological, chemical and radiological threats.

• An effective public health front line defense depends on the ability of PHLs, clinical partners, commercial labs, first responders and federal agencies to respond together.
Laboratory Response Network

- Sentinel Labs: recognize, rule-out, refer
- Reference Labs: confirmatory testing
- National Labs: definitive characterization

150
25,000
Past Responses

• 1999 West Nile Virus
• 2002 Severe Acute Respiratory Syndrome
• 2009 Pandemic H1N1 Influenza
• 2013 Ebola Virus Disease
• 2015 Zika Virus
Current Zika Virus Response

• Most PHLs rely on CDC developed tests
• CDC Zika MAC-ELISA approved Feb 26th 2016 under the FDA EUA
• CDC Trioplex rt RT-PCR assay was approved March 17th 2016 under the FDA EUA
• Other Commercial tests approved from April 28th 2016 (Focus Diagnostics) through September 28th (ARUP Laboratories' Zika Virus Detection)
Challenges with Test Implementation

• Not all PHLs have extensive experience performing MAC-ELISA tests
• MAC-ELISA is labor intensive, days to results, cross reactive with other Flaviviruses
• Testing algorithms are complex, different sample types, symptomatic vs asymptomatic pregnant women etc
Other Testing Needed

• Testing for Dengue, Chik, WNv, SLE
• Plaque Reduction Neutralization (PRNT) testing to confirm IgM results and differentiate Flaviviruses
• Convalescent samples
• PHLs requested to perform mosquito testing
• AZ PHL responding to a Measles outbreak also
Surge Testing Planning

Zika Surge Testing
Weekly Capacity Levels

Level 1
Baseline Testing
M-F 8am-5pm
2 Laboratorians
100 Total IgM ELISA
150 Total Trioplex

Level 2
Surge Testing - Routine
Laboratory Hours
M-F 8am-5pm
4 Laboratorians
288 Total IgM ELISA
305 Total Trioplex

Level 3
Surge Testing - Expanded
Laboratory Hours
M-F 7am-8pm, Sat & Sun 8am-5pm
6 Laboratorians
522 Total IgM ELISA
561 Total Trioplex

MOA partners alerted to potential activation
MOA activated, specimens exceeding capacity are shipped to partner laboratories
Working with Commercial Labs

- Working with 2 largest commercial labs in AZ, who were performing RT-PCR for Zika
- Electronic notification to Local / State Health Depts when Zika testing ordered, results reported
- Discussing discordant test results
- CDC working with Commercial labs to implement the CDC IgM MAC-ELISA
Testing Demand Increase

- PHLs started to see an increase in testing particularly in Florida once local transmission occurred.
- “Pregnant Women Anxious as Florida’s Zika Test Results Take Weeks” NYT Sept 12th 2016
- Commercial labs were seeing an increased demand for testing
- At this time there is no end in sight
Commercial labs / PHLs and Preparedness Final Thoughts

• PHL’s, Commercial labs, Federal labs response to Zika testing is critical
• Is there a way to get commercial assays EUA approved more rapidly (challenges obtaining positive clinical samples)
• In most cases Commercial labs may have higher throughput than PHLs
Commercial labs / PHLs and Preparedness Final Thoughts

• LRN has an overall surge testing capacity however even this could be overwhelmed with local transmission in multiple states

• Do commercial labs have a role to play with surge testing not only with Zika but with other emerging infectious disease outbreaks?

• CDC could consider providing protocols to commercial labs and PHLs simultaneously

• Preparedness costs money. Reductions in PHEP have impacts on outreach to sentinel labs