

Clinical and Public Health Laboratory Preparedness and Response

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Presenting To

Clinical Laboratory Improvement Advisory Committee
CDC Atlanta

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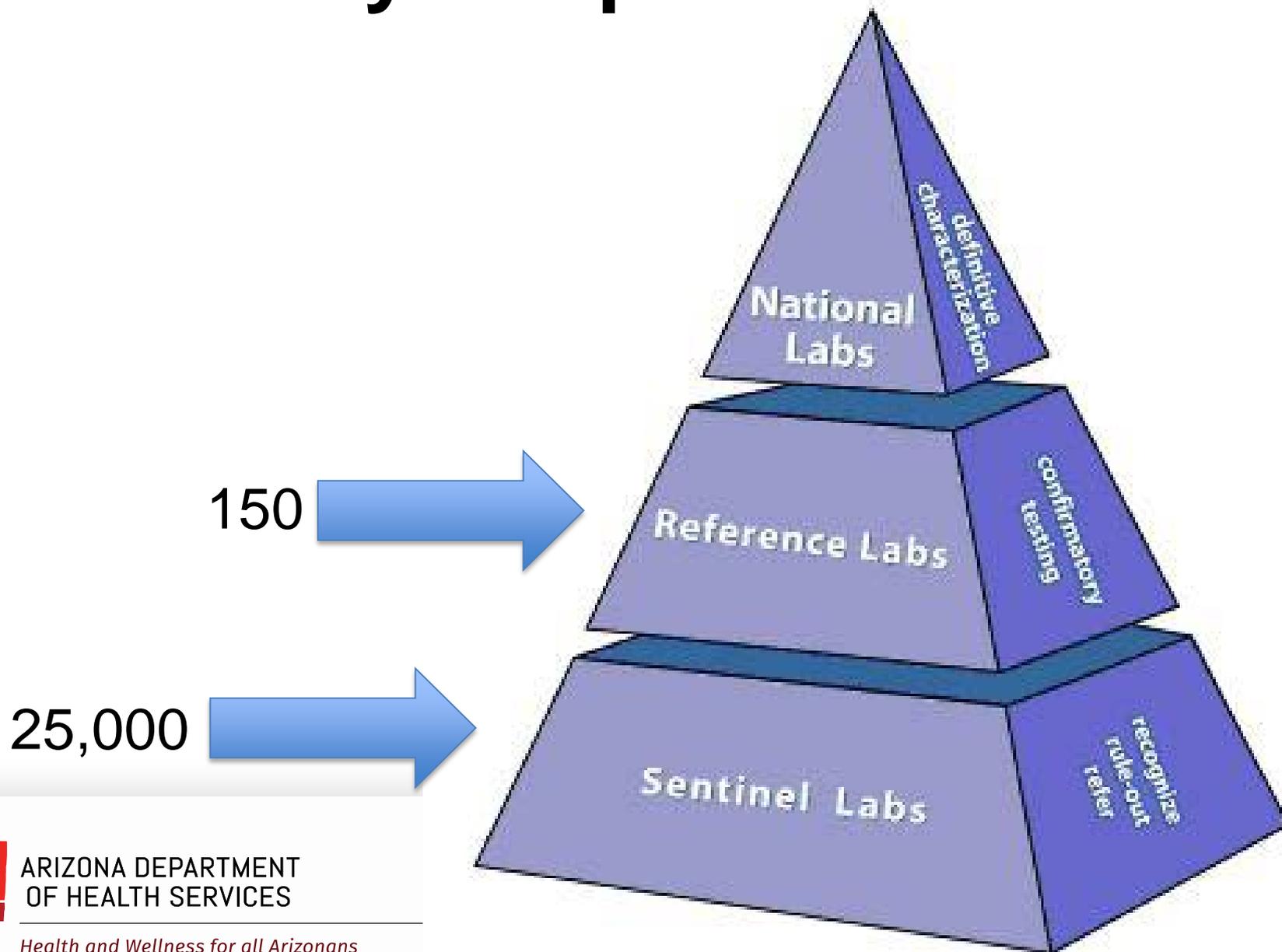
Health and Wellness for all Arizonans

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

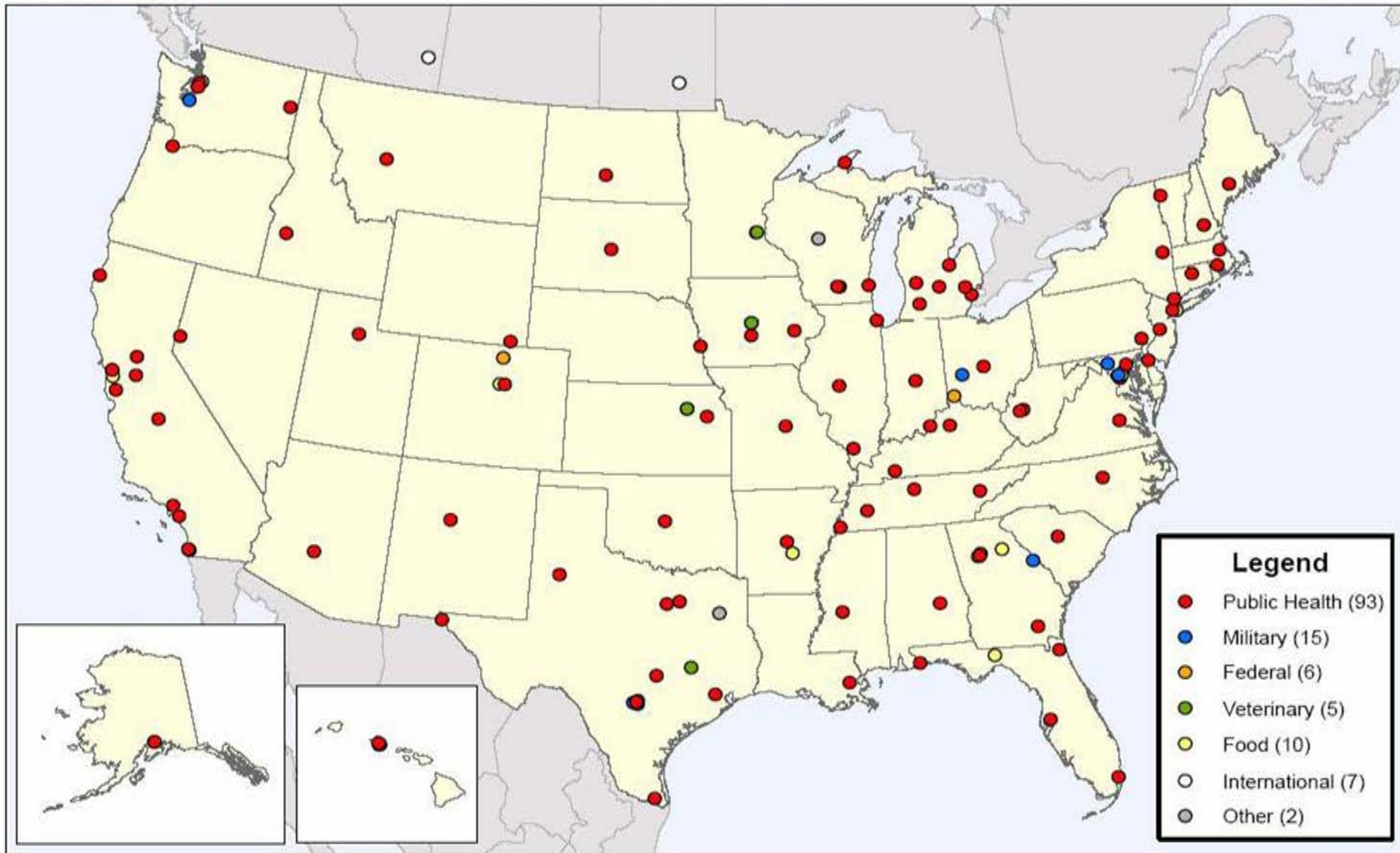


Laboratory Response Network



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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



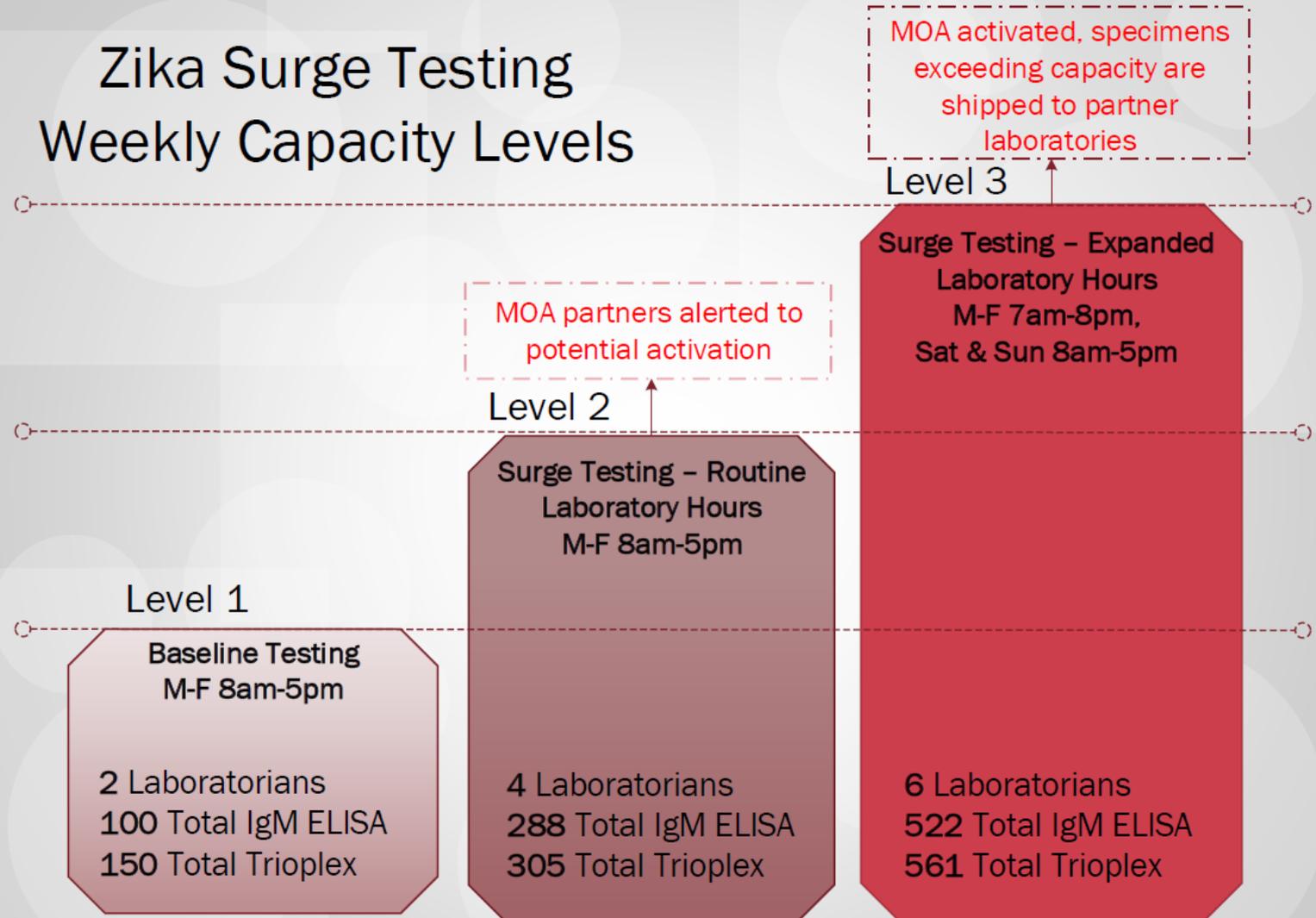
Other Testing Needed

- 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



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 over all 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



THANK YOU

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