



# ZIKA VIRUS TESTING

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- ▶ **CDC Zika MAC ELISA (IgM)**
  - ▶ Emergency Use Authorization (EUA)
- ▶ **CDC Trioplex (Dengue, Chikungunya and Zika)**
  - ▶ EUA
  - ▶ Human serum, urine and other specimens if paired with serum
- ▶ **In-house (Lancotti-based) rtRT-PCR method**
  - ▶ Verification of performance characteristics required (CLIA)
  - ▶ Human serum & urine

TESTS

- ▶ **FDA announced EUA for additional tests:**
  - ▶ **Aptima Zika Virus Assay (Hologic, 6/17/2016)**
    - ▶ <http://www.hologic.com/products/clinical-diagnostics-and-blood-screening/assays-and-tests/aptima-zika-virus-assay>
    - ▶ <http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM507503.pdf>
  - ▶ **Quest Diagnostics (4/28/2016)**
    - ▶ <http://newsroom.questdiagnostics.com/2016-04-28-Zika-Test-from-Quest-Diagnostics-Authorized-by-the-FDA-for-Emergency-Use>
    - ▶ Planning to offer serological services if approved by FDA (EUA)

**OTHER TESTS**

- ▶ The BTRL started testing on *May 18, 2016*
- ▶ By *6/21/16*, PHEL had accessioned specimens from 174 patients
- ▶ 50 patients were tested by the 2 rtRT-PCR methods (*5/18/16 – 6/21/16*)
  - ▶ Method utilization is being reassessed
  - ▶ Conflicting results from the 2 rtRT-PCR methods will no longer be reported via LIMS
    - ▶ e.g., Trioplex positive, but Lanciotti negative
- ▶ 2/50 (4% so far) were positive for Dengue virus by rtRT-PCR
- ▶ 12/50 (24% so far) were positive for Zika virus by rtRT-PCR
- ▶ Chikungunya virus has not yet been identified in any of the specimens

PRELIMINARY STATISTICS (LOCAL TESTING ONLY)

- ▶ **CDC-LRN and APHL have requested information about NJ's capability, capacity and availability to conduct Arbovirus tests for specimens from other States**
  - ▶ A high surge of specimens is anticipated in the coming weeks
  - ▶ As of mid-June, some States were still in the early stages of assay development and verification
- ▶ **Staffing and funding issues**
- ▶ **Verification of Lanciotti rtRT-PCR assay performance characteristics**
  - ▶ Additional specimen types

## NEWS & CHALLENGES

- ▶ Dengue high viremia vs Zika low viremia
- ▶ Dengue may enhance Zika
- ▶ Higher ratio of female-to-male infection? (Zika)
- ▶ Who to test? Which specimens to test?
- ▶ Patients viremic prior to onset of symptoms
- ▶ CDC Zika MAC-ELISA is not automated (big problem)
- ▶ Pregnant staff handling Zika virus cultures?
- ▶ Baseline testing for lab workers?
- ▶ Which virus will come next?

## NEWS & CHALLENGES (ASM MICROBE 2016)



- ▶ <http://www.cdc.gov/zika/geo/active-countries.html>
- ▶ [http://www.cdc.gov/mmwr/zika\\_reports.html](http://www.cdc.gov/mmwr/zika_reports.html)
- ▶ Zika Virus Outbreak on Yap Island, Federated States of Micronesia. *N Engl J Med* 2009; 360:2536-2543.
- ▶ Sirohi et al. The 3.8 Å resolution cryo-EM structure of Zika virus. *Science* 22 Apr 2016: Vol. 352, Issue 6284, pp. 467-470
- ▶ Kostyuchenko et al. Structure of the thermally stable Zika virus. *Nature* (2016). Published online 19 April 2016.
- ▶ Blitvich and Firth. Insect-Specific Flaviviruses: A Systematic Review of Their Discovery, Host Range, Mode of Transmission, Superinfection Exclusion Potential and Genomic Organization. *Viruses* 2015, 7(4), 1927-1959.



## REFERENCES

- ▶ New York Department of Health and Mental Hygiene
- ▶ CDC, Laboratory Response Network (LRN)

# ACKNOWLEDGMENTS