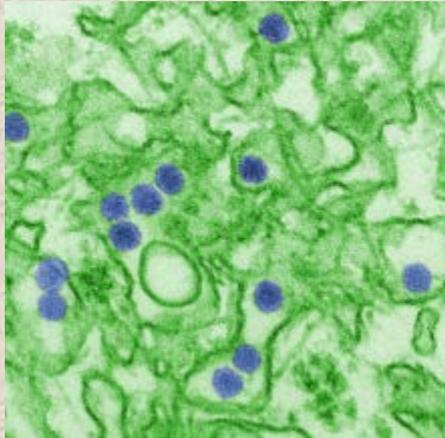
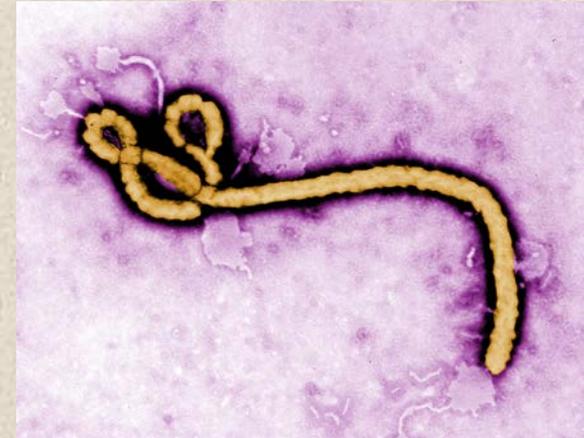


Zika Testing: More Challenging than Ebola?



VS.



Ebola vs. Zika

- Implementation of Ebola EUA rRT-PCR test was straightforward
 - » No need to change protocol to increase throughput or to add more specimen types
- Testing for Zika is more complicated
 - » RT-PCR initially was LDT only using serum but several labs worked to validate urine
 - » EUA MAC-ELISA released
 - » EUA RT-PCR Trioplex for serum and urine released



Zika PCR: LDT vs. EUA

- Validation for the Ebola test was very simple and was acceptable for CLIA
- Zika LDT required additional validation
 - » Labs had to find specimens from other labs or spike samples to validate
- Many labs just decided to wait for the Trioplex to be released



Zika PCR: EUA

- Triplex assay had several options for automated extraction
- Some labs did not have the instrumentation listed in the EUA
 - » Labs had to validate the assay as an LDT if using other extractors



Zika Serology: LDT vs. EUA

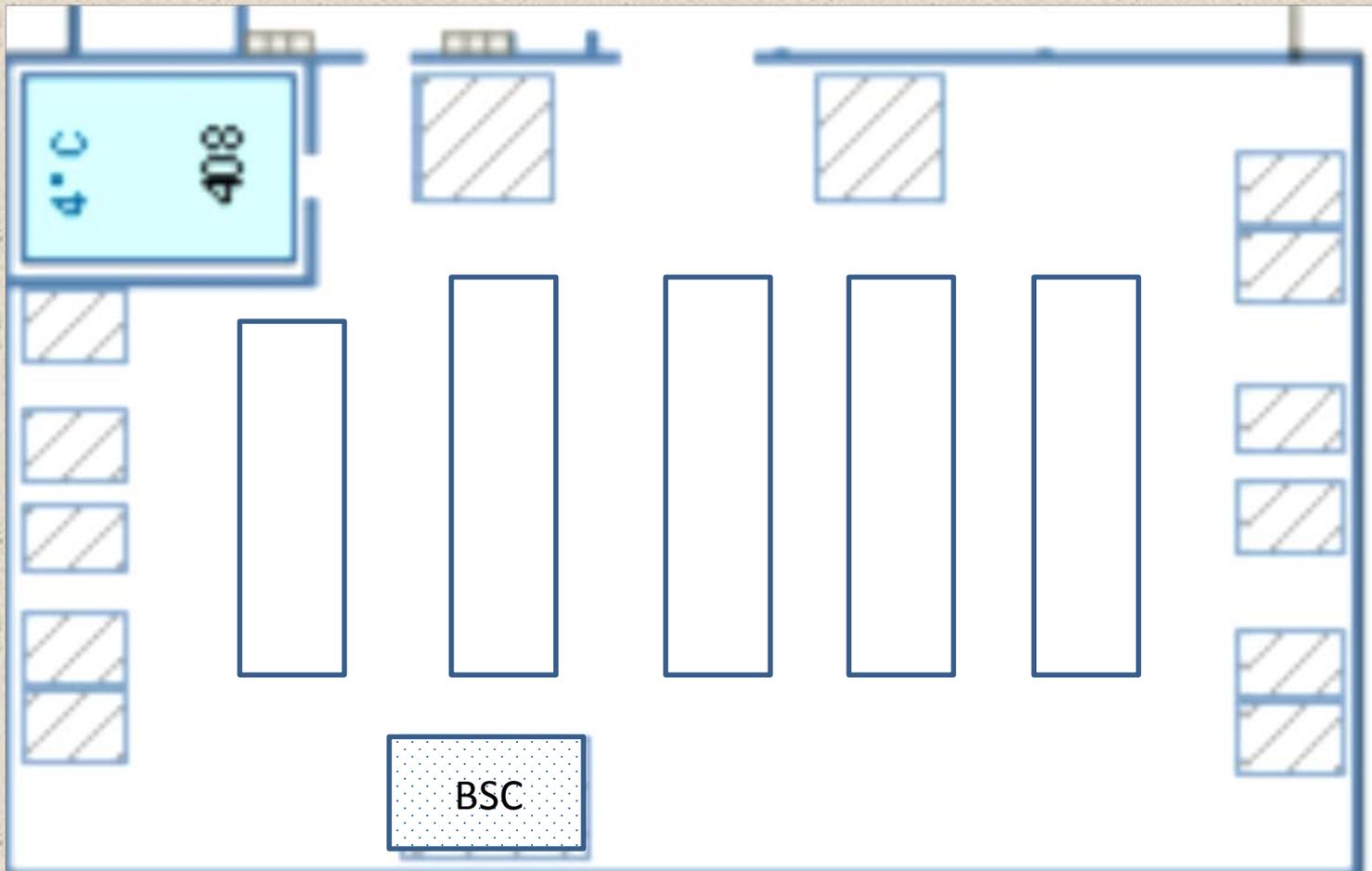
- Labs moved early on to implement the LDT version of the Zika MAC ELISA
- Were familiar with the MAC-ELISA assay and felt confident that given the controls, antigen, and antibodies could implement quickly
- Release of the EUA Zika MAC-ELISA was immediately welcomed but with reservations



Serology: What BSL?

- Chikungunya being listed as a BSL-3 organism caused difficulties in implementing the test
 - » Serology typically performed testing under BSL-1 or -2 lab conditions
 - » BSL-3 located on different floor
 - » Serology staff not trained in BSL-3 practices
 - » Two groups in one lab; one using BSL-2/3 practices and one using BSL-1/2 practices – mixed messages

Serology: What BSL?





Retrofitting the Lab

- Moved equipment to be dedicated for testing
- Added plexiglass to isolate equipment and testing area
- Placed plate washer and plate reader in Class I BSC



Rearranging Workflow

- Developed unidirectional workflow
- Isolated the Class II BSC when Zika testing being performed
- Worked with BSO and safety officer to develop procedures specific for the new BSL practices



Training

- Rapid training of staff used to only working at a BSL-1 level
- Used previously developed online BSL-3 training for theory and practice
- Practice runs of the procedure
- Used a buddy system for working in BSL-3
 - » Helped staff to feel more comfortable working at a higher biosafety level



Moving Forward

- EUA provides the ability to rapidly deploy assays during an emergency
- Flexibility is needed to respond to changing situations during emergency responses
- LDTs play a role in ensuring labs can provide effective testing to meet patient needs