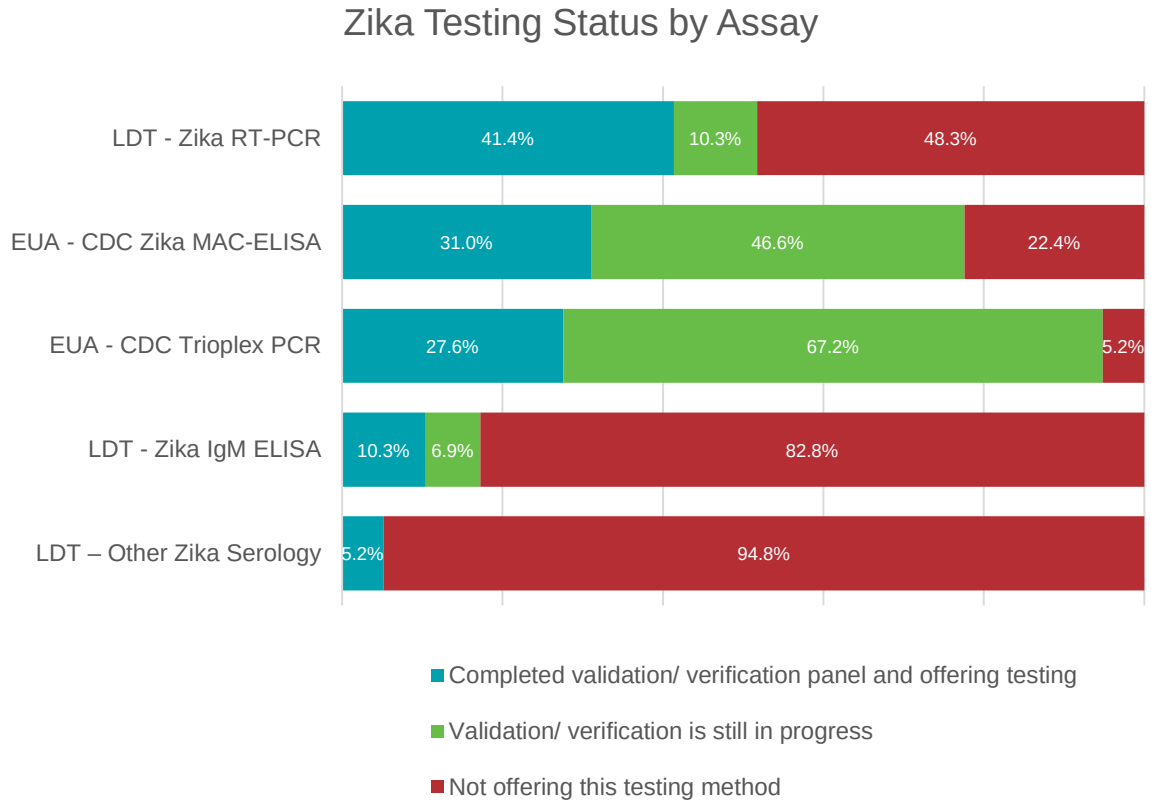
Public Health Laboratory Zika Virus Testing Capacity Survey Summary Report

The recent re-emergence of Zika virus in the Americas and potential links to neurological and auto-immune complications have placed health systems across the globe on high alert. To assess the current Zika virus testing capacities of public health laboratories (PHL), the Association of Public Health Laboratories (APHL) fielded a survey from March 25, 2016 to April 25, 2016 to 58 PHLs (all state and select local PHLs). All 58 (100%) PHLs responded to the survey and provided data indicating that 37 (64%) of PHLs provide Zika virus testing. The following tables and figures below provide descriptive summary statistics of the aggregate responses of all the PHLs that participated in the survey.

1. Please complete the table below regarding your laboratory's status with Zika Virus testing. Please check all that apply. (n=58)

	Not offering this testing method		Requested testing materials and/or protocols from CDC		Received materials from CDC		Completed validation/ verification panel and offering testing	
	n	%	n	%	n	%	n	%
LDT - Zika IgM ELISA	48	82.8%	1	1.7%	5	8.6%	6	10.3%
LDT - Zika RT-PCR	28	48.3%	6	10.3%	9	15.5%	24	41.4%
LDT – Other Zika Serology	55	94.8%	0	0.0%	0	0.0%	3	5.2%
EUA - CDC Zika MAC-ELISA	13	22.4%	16	27.6%	27	46.6%	18	31.0%
EUA - CDC Trioplex PCR	3	5.2%	12	20.7%	40	69.0%	16	27.6%



1a. If you have validated a serology assay as a LDT, would you prefer to use your LDT? (n=6)

Answer	Response	%
Yes - Briefly explain why you prefer to use your LDT	4	66.7%
No, prefer to switch to EUA CDC Zika MAC-ELISA	2	33.3%
Total	**6**	**100.0%**

Yes – Explanations why PHLs prefer their LDT
No LRN reporting requirement at this time, although not sure if CDC will continue to provide reagents if we do not use the EUA.
If use LDT would not have to report through LRN. If had to log in specimens and report through LRN we would not have time to actually test the specimens. We are concerned CDC will not continue to supply reagents if we don't use EUA. Actually don't know the difference between the 2 assays except for the reporting requirement.
Our decision to switch or not switch to FDA EUA MAC-ELISA depends on the results of an on-going conjugate evaluation. Our initial experience has demonstrated that the performance of the EUA approved conjugate is sub-standard when compared to existing conjugate that we have been using in the LDT. Also, the limited specimen acceptability criteria and the future availability of adequate supplies of the EUA MAC ELISA are concerns for us.
Short turnaround-time

1b. If you have validated a PCR as a LDT, would you prefer to use your LDT? (n=24)

Answer	Response	%
Yes - Briefly explain why you prefer to use your LDT	9	37.5%
No, prefer to switch to EUA CDC Trioplex PCR	15	62.5%
Total	**24**	**100.0%**

Yes - Briefly explain why you prefer to use your LDT RT-PCR
We are offering the test to males as well as females. Using our LDT will keep specimen workflow smoother than trying to triage every sample we receive. We may use the Trioplex with pregnant females who have travel history to test for all three agents at once. Physicians may not request all three agents. Also, the Roche MagNA Pure LC final extraction volume (60uL) may not be enough if testing needs to be repeated.
At this point, the CDC assay is not amenable to our automated extractors. Because of our high volume, we need to use automation. Also, the electronic reporting requirements are not feasible at this time.
No LRN reporting requirement at this time. Can use other specimen types – e.g. saliva and semen. EUA not validated for the QiaCube. Concerns over sensitivity of the multiplex EUA compared to LDT single plex assay.
Don't have to report through LRN. Can test saliva and semen with LDT. MagnaPure extraction volume is different from other assays performed, so would have to do a separate extraction run just for Zika specimens (could not include Influenza, norovirus, etc. on same extraction run).
For the specimen types (urine, serum, CSF amniotic fluids) that have been approved for use in the CDC EUA assay, would prefer to use the EUA assay. However for other non-approved specimen types (semen, fresh tissues, NP/OP swabs, etc.), we will continue to use the LDT. Additionally since Trioplex assay cannot distinguish between the different serotypes of dengue viruses we plan to reflex to the other CDC FDA approved dengue PCR assay if the Trioplex assay is reactive for dengue. Similarly because there is only one PCR gene target for Chikungunya in the Trioplex, we would feel more comfortable if Chik reactive specimens from the Trioplex assay would be reflexed to a supplemental existing LDT test that can detect additional Chik. Gene targets to confirm the reactivity of the Trioplex assay. Also the future availability of adequate supplies of the Trioplex assay is a concern for us.
No
With the LDT IFA we can accommodate 60 patients/day routinely
#1 reason - extraction methods required by the EUA are not feasible for us to use for this testing. We have had discussions and were told that we cannot use a different extraction method even with full in-house approved validation. No requirement to double data enter to report all results through LRN RM. With the LDT, we can test patients that meet our testing criteria which are not the same as the CDC testing criteria. We have also heard that the sensitivity of the EUA is lower than that of the LDT. Many positives in serum are right near the Ct cutoff on the LDT, and we are concerned that we will have false negatives due to lack of sensitivity if we move to the EUA assay. Based on data from other tests, the MagnaPure does not have great yield compared to other extraction methods, which may be part of the issue. The multiplexed-ness of the EUA is very attractive and we would use it if the above issues were addressed.
Will use LDT PCR test until the multiplex testing is validated

2. Do you have capability to perform Plaque Reduction Neutralization Testing (PRNT) for any pathogen? (n=58)

Answer	Response	%
Yes (go to 2a)	10	17.2%
No	48	82.8%
Total	**58**	**100.0%**

2a. Please describe your laboratory plans for Zika PRNT. (n=10)

Answer	Response	%
Do not plan to implement PRNT for Zika virus	4	40.0%
Plan to implement PRNT for Zika virus but do not offer the test	4	40.0%
Have implemented PRNT for Zika virus and offer the test (go to 2b & 2c)	2	20.0%
Total	**10**	**100.0%**

2b. Are you working with CDC to become a laboratory qualified to confirm results obtained from the CDC Zika MAC ELISA with PRNT? (n=2)

Answer	Response	%
No	1	50.0%
Yes, in the process of working with CDC to become a qualified PRNT laboratory	0	0.0%
Yes, completed the process and are a qualified PRNT laboratory	1	50.0%
Total	**2**	**100.0%**

2c. Will you be willing to provide surge capacity for PRNT? (n=2)

Answer	Response	%
Yes - Provide estimated number of additional specimens you are able to test weekly	1	50.0%
No	1	50.0%
Total	**2**	**100.0%**

Estimated number of additional specimens reported by PHLs
50

3. What automated extraction platform(s) does your laboratory have available and is able to utilize for arbovirus testing? Please check all that apply. (n=58)

Answer	Response	%
Roche MagNA Pure Compact	35	60.3%
Roche MagNA Pure LC 2.0	34	58.6%
Qiagen QIACube	19	32.8%
bioMerieux NucliSENS easyMAG	18	31.0%
Other – please specify	10	17.2%
Roche MagNA Pure 96 instrument	5	8.6%
None of the above	4	6.9%

Other specified responses
We have a MagMax extractor. May purchase the Qiagen QiaCube, especially if Zika is offered on it.
older model magnapure
Kingfisher Flex
*Our Qiacube is a 96 well high throughput instrument, which is not on the EUA approved list
We have MagNA Pure 1.0, and easyMAG, but cannot use for the EUA assay
Qiagen Bio-Robot 96 well
Qiagen QiaSymphony, Qiagen EZ-1 Advanced XL, Kingfisher-24 (MagAttract)
Neither of the automated platforms that we have (Roche MagNA pure Compact and Qiagen QIACube) are currently available in the BSL3 since they are used for other work.
King Fisher
We have others, but EasyMag is what we are using for Zika based on location and capacity/throughput.

Automated Extraction Platforms Utilized by PHLs for Arbovirus Testing