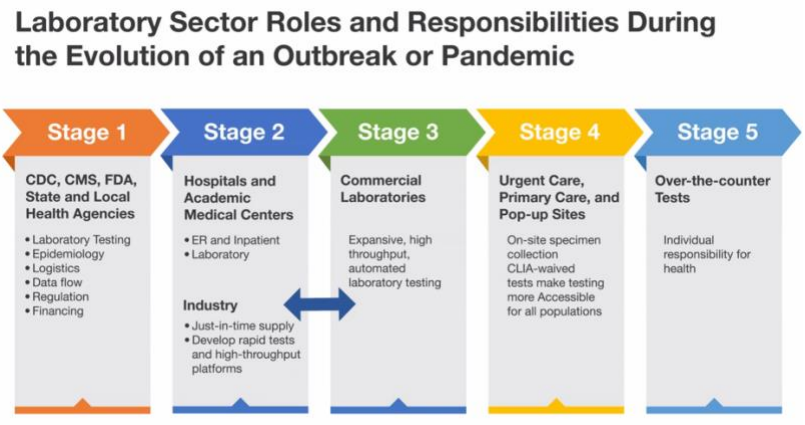
CSTE/APHL/CDC Lab/Epi Thought Leaders Workgroup Meeting Notes

Date:	**Tuesday November 29, 2022**
Start/End Time:	**2-3PM ET**

Notes

#	Topic	Items
1.	Open and welcome	**Open and Welcome – Marci Layton, CSTE**

2.	Scaling Laboratory Testing and Capacity During Emerging Outbreaks	**Scaling Laboratory Testing and Capacity During Emerging Outbreaks, Scott Becker, APHL**
		• Scott presented a similar presentation at ICEID and a number of people were getting in touch about this issue with interest and to express a need for progress on this topic
		• Today's presentation is meant to be thought provoking for discussion
		• APHL has as a highest priority – improving laboratory response
		• Modernizing PHL laboratory response
		• What is the role of the PHL system in an outbreak?
		  ○ Answer: Readiness, for both the initial threat detection, and broad testing in the early stages of an outbreak
		• Feedback from member: Broad testing might be framed as bridge testing… to get to a point of commercial capacity
		 
		• What should we be doing about this?
		  ○ These issues are all fixable if we approach them with the aim of developing an accessible and flexible public health laboratory system
		• PHL were criticized for being slow at the beginning of MPOX, but we had a slow test
		• **Stage 1: As soon as possible**. What are the most critical things we need to do sooner rather than later
		  ○ Operationalize surge testing within the network to relieve overburdened sites
		  ▪ We did not do this with MPOX. CDC activated a small number of commercial laboratories to address this as we didn't have the ability to get the specimens to the PHLs with capacity.
		  ▪ Sudanvirus Ebola – LRN labs and some PHLs, a subset have the test.
		  ○ We need to modernize the LRN assays
		  ▪ Automate extraction methods
		  ▪ Optimize for high throughput on multiple platforms
		  ▪ Enable testing at BSL-2 with pre-determined inactivation protocols

- Ensure efficient courier services are at the ready
- We need to address the tension between the gate keeping function and the urgent need for broad testing

- **Stage 2: In the Near Future**
  - Develop, with epidemiologists' input, a 24/7 national hotline for physicians to order tests from PHLs simply and efficiently
  - Every jurisdiction must have an Electronic Test Order and Reporting (ETOR) for routine and emergency testing, including state PHL to CDC
  - Develop a playbook for diagnostic response
    - APHL is working with Brown University to develop a playbook and will involve CSTE as well
  - Contract with manufacturers to support J.I.T. manufacturing of tests, and development of rapid antigen- and PCR-based tests, as appropriate
  - Further the work with CSTE to develop a baseline set of essential data for initial test orders
- *Discussion:*
  - PHLs have responded as best they could. But, challenges were out of PHL control. The rules were hampering PHL ability to respond in the best way possible. The overarching block/origin of much of the delay resides to a great degree with our regulatory authorities: FDA, CMS/CLIA. The burden on labs has expanded to include control of many pre-analytical components (shipping, temp control, medium types, etc.) that have prevented us from TESTING. Many of these components are out of the lab's control. With novel agents, we need LEEWAY to do testing. Yes, we want reliability in our results, but we also want to TEST. The Dx PLAYBOOK should address this -- how can we streamline the validation process to get ACCURATE and RELIABLE TESTS online ASAP.
  - Supply chains are another factor that had great negative impact on our ability to TEST/respond.
  - ETOR relates to data modernization.
  - APHL will work this year on relationship building with ASPR, as there can be significant improvement in our understanding of ASPR and their role and their understanding of our role in a PHE.
  - Resources at CDC for these efforts are limited. We need to work on advocating for resources for this purpose, similar to DMI
  - We now have much documentation of the need to expand response beyond LRN.
  - It is hard to anticipate what will be needed from laboratories next and building flexibility within/beyond the plans is very important.
  - Needs to be some kind of quick switch over to commercial
    - That is the plan for the playbook
    - This system was designed 22 years ago for something very different. It was not designed for all infectious disease response.
  - Need to address workforce at the PHLs 24/7
  - Proposed data elements and the importance of electronic ordering
    - All the different jurisdictions have different requirements
    - Need predefined core elements to meet criteria for testing across country
    - CSTE can share the initial list of data elements drafted
  - Need to better coordinate and understand the different roles and each other's aims – commercial labs and PHLs
  - One challenge with MPOX was using the correct platform – are there approaches that are more universal platforms?

		▪ Challenging. Manual extraction does not require platform, but is slow. ▪ There are still a lot of laboratories doing manual extraction because of their biosafety procedures ▪ Not all agents are the same ▪ This needs to be addressed in the playbook ▪ COVID-19 is very different than Sudanvirus, for example ▪ Needed different platforms during COVID-19 because of the supply chain ○ Type of and range of specimens is important to consider in testing roll out and important for our ability to understand the pathogen and epidemiology ○ There was a gap in understanding between jurisdictions and CDC as well with MPOX and the potential role of commercial labs ○ Need to expand partnerships with academia, because there are a lot of things they can do when working with public health ○ With COVID-19 ramp up, and influx of pop up commercial labs we had no idea what level of competency they had, if they were doing good or valid tests, etc. And then needed to navigate and communicate the results and their validity. There needs to be better control. ○ A huge recruitment of PHL scientists to go to the private sector caused an issue with the workforce ○ Supply chain issues also created an environment for poor non-functioning tests ○ Something to consider in the playbook would be the post-approval validation activities. SARS-CoV-2 showed dynamic variation in test accuracy after initial authorization and the process of revisiting the suitability of tests over time. ○ How do we work with the commercial sector on sending specimens to the PHLs ○ We may need to think about incentivizing clinical/commercial labs to get samples. ○ Plan to keep this dialogue going with APHL, CSTE, working with colleagues at CDC ○ CSTE would like to work on taking some of these topics and make progress w APHL ○ National triage line: Would STLTs need to discuss a process for some to accept or some not to use it, if they have small volumes and want more gatekeeping? ○ There is also a billing efficiency for healthcare facilities to work with their commercial lab ○ MPOX: A few jurisdictions could not keep up with demand and CDC asked whether they wanted to trigger to the commercial labs, but this didn't happen fast enough. ▪ Should have surge capacity within LRN. Need to operationalize this better. ○ When things move to commercial, there was frustration from the clinicians, there needs to be more clear communication to the clinician community. ○ Challenges will not always be the same in each jurisdiction. ○ Epis have to create instructions for clinicians on how to collect specimens. This is something that CDC and APHL could help make universal and easily distributed.
4.	Workgroup updates	• We would like to debrief re: the TL call in general, lessons learned, how best to stand up again during a December or January meeting. • Then, will sunset with ability to rapidly reconvene as needed. • Future topics: ○ December or January: ▪ Debrief ▪ CDC CORVD
Next Meeting: December/January 2022 - Date TBD		