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# Lab/Epi CSTE/APHL/CDC Thought Leaders Workgroup Call Meeting Minutes and Action Items

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| Date: | **Tuesday May 31, 2022** |
| Start/End Time: | **2:30-3:30PM ET** |

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| 1. | Open, Welcome, and Announcements | Open and welcome, **Andrew Adams, CSTE**<br><br>Announcement: CSTE Advanced Molecular Detection (AMD) Workgroup and Webinar Series – **Lindsay Jordan Pierce, CSTE**<br>• CSTE AMD Workgroup:<br>  ○ CSTE will host bi-monthly workgroup conference calls and sharing of relevant resources and communication materials<br>  ○ The AMD Workgroup will contribute webinar presentation topics based on member interest and needs<br>  ○ **Please complete the interest form via the link provided** HERE **if you would like to participate in the CSTE AMD Workgroup.**<br><br>• CSTE AMD Webinar Series:<br>  ○ CSTE will host a bimonthly AMD webinar series dedicated to knowledge sharing on specific AMD topics in the months between workgroup calls<br>  ○ **Wednesday, June 8, 2022 at 4:00 pm EDT - "Problem-solving Collaboration Between Laboratory and Epidemiology Programs on COVID-19"**<br>  ○ Participants will hear from Boston University's COVID-19 pandemic management team and the Connor Lab of the National Emerging Infectious Diseases Laboratories (NEIDL) who have collaborated to link traditional contact tracing with genomic sequencing as an effective approach for informing public health protocols to limit disease spread in a university environment. This hybrid model for disease tracking aligns the "person-story" and "virus-story" and has provided more clarity than either approach alone.<br>  ○ **Need to register: CSTE AMD webinar Registration Link** NOTE: Registration is limited to 500 participants.<br>  ○ If you have any questions about this webinar, please email Lindsay Jordan Pierce at lpierce@cste.org with "AMD Webinar" in the subject line. |
| 2. | Performance of diagnostic tests for known SARS-CoV-2 Variants and Plans for Optimization of Diagnostics for Future Emerging Variants | Performance of diagnostic tests for known SARS-CoV-2 Variants and Plans for Optimization of Diagnostics for Future Emerging Variants – **Tim Stenzel, FDA**<br>• BA.4 and .5 have been growing even though the numbers are currently small, seems to have a growth advantage<br>• Only 4 confirmed cases of diagnostic tests that did not detect Omicron:<br>  ○ Three were molecular tests that lost signal for Omicron, they were all two target tests. Therefore, FDA has advised multiple targets for molecular tests.<br>  ○ One antigen test, which was with a sequence that was well below 5% of sequences. There is a published report about this. Has not been a frequent mutation in the US population.<br>• FDA does post the impact of variants on tests on their website.<br>• The impact has not been significant in loss of sensitivity for molecular testing.<br>• Discussion of antigen test sensitivity during Omicron wave is on the FDA website.<br>• Impact of prior infection or vaccination on diagnostics:<br>  ○ With UMASS, looked at prior infection and vaccination and all available data to-date suggests that there isn't a large impact on diagnostics from vaccination or prior infection. |

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| | | • Low positives are defined as a CT over 30 on the Roche assay. Among these low positives, the antigen testing sensitivity decreases, therefore an increase in false negatives (positive percent agreement of ~60% among symptomatic individuals, therefore, missing 40% of Omicron infections among symptomatic with antigen testing alone) or potentially higher with recent sublineages<br>• In order to authorize antigen tests, FDA displays all the study data in the instructions for use and authorization<br>• Because of other independent tests performed, they do not believe that the antigen tests themselves are less sensitive than those prior to Omicron. Some of the newer tests appear to be analytically superior to the prior tests, but perhaps there are changes with the virus. Under active study because currently numbers are small and early data.<br>• There is a recommendation for serial testing in symptomatic and asymptomatic people (recommended to do 2-3 tests with antigen testing over three days)<br>• Discussions about public messaging about this point including need for serial antigen testing and staying home if sick.<br>• Some STLTs have heard concerns raised re: BA.4 and BA.5 detection by Ag testing, but not clear yet if BA.4 and BA.5 will be detected any less. This will be studied further.<br>• Bioinformatics predicts no loss of signal. The bioinformatics pipeline – high resolution epitope mapping modeling – suggests that we do not have a prediction of a further loss of signal for Omicron BA.4 or BA.5. However, currently are collecting these to do wet testing, to confirm this by testing on samples. |
| 3. | APHL SARS-CoV-2 Genomic Surveillance Document | APHL SARS-CoV-2 Genomic Surveillance Document – **David Wentworth, CDC and Kelly Wroblewski, APHL**<br>• CDC is providing recommendations for the minimum number of specimens that should be sequenced by STLTs for local/regional situational awareness and to support national genomic surveillance.<br>• STLT sequencing can also improve timeliness.<br>• NS3 guidelines for selecting the specimens.<br>• Recommend sequencing about 300 SARS-CoV-2 positive samples on a weekly basis, with one week TAT. This number was set from calculations re: a detection level minimum.<br>• Some of the tools to help improve timeliness are in the document, such as performing the most recent samples first, and work your way backwards, critical for identifying emerging variants.<br>• Jurisdictions with large populations such as those with 20M or more population (CA FL, etc.) may want to do 0.5 to 0.1% because of a large geographic region and population size.<br>• There has been a tremendous increase in tagged sequences.<br>• Jurisdictional data are published online, but needs to be collected over multiple weeks to be meaningful, therefore takes time by the time they are available. So, this recommended approach would help with speed of this jurisdictional data.<br>• However, quality is also important. If you have a lot of sequences but not great quality, it is not helpful, so quality also needs to be improved.<br>• Want a broad spectrum of sequences from those with and without severe disease.<br>• The focus of this work is to understand the regional situation which will impact how well monoclonal antibodies work in each jurisdiction, and to know what is circulating.<br>• Discussed concerns re: the PHLs having enough resources to do this, including space, staff, etc.<br>  ○ This was why 300 samples weekly was chosen, rather than a percentage of cases, as 300 is more manageable, and a percentage of cases during a surge may not be manageable.<br>• Currently some STLTs are getting sequencing done through contracting with CDC funding.<br>• Some STLTs have concerns re: the approach to the sample (more than the absolute number of the sample), as it is not random.<br>• Guidance requested on automation, how to increase throughput, speed of testing, and improve quality with technical support and guidance down the road |

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| | | • Question raised re: whether the CDC contract WGS labs are aiming to complement the 300 per week per jurisdiction or replace? → The contract labs are aiming to complement the PHLs. The long term goal is that these contract labs decrease over time. Better to have the STLT perform and develop capacity for both SARS-CoV-2 and other pathogens. There has been an enormous transition of capabilities over the course of the pandemic, a huge step forward.<br>• STLTs raised the challenge now is getting sufficient positive samples to sequence. With higher CT's which usually do not sequence well, the problem is intensified.<br>• **The document is available on the APHL website to members. Additionally, shortly after the call Kelly will share the open link for those who are not APHL members.**<br>• **Questions re: the recommendations: David Wentworth email: dwentworth@cdc.gov** |
| 4. | OpET and ICATT Data Dashboards | ICATT Data Dashboards – **Carrie Pierce, CDC**<br>• Expansion of Screening and Diagnostics Task Force<br>• CDCs Operation Expanded Testing program (OpET) and Increasing Community Access to Testing program (ICATT)<br>• Dashboard objectives: at present STLTs receive weekly and monthly testing and site data. Goal is to provide greater access to STLTs to make informed decisions<br>• Developed two dashboards within HHS Protect, accessible to the STLTs, which will include two tabs added to the 360° view: A tab for the OpET and a tab for ICATT with modifiable metrics<br>  ○ High level summary overviews<br>  ○ Testing metrics and trends<br>  ○ Information on individual sites<br>• OpET: Testing volume, percent positivity, equity metrics, etc.<br>• ICATT same as above and number of pharmacy and surge sites, and information on individual sites.<br>• Slides to be sent out to this group<br>• Current status - phased roll out:<br>  ○ 7 pilot states - showcased the dashboard May 16, 2022.<br>  ○ June timeframe - roll out to all the jurisdictions<br>• User documentation provided<br>• Would like feedback from STLTs to enhance usefulness: eocevent588@cdc.gov |
| 5. | CSTE/APHL/CDC Lab/Epi Thought Leaders Workgroup Call Frequency and Scope | Workgroup Call Frequency and Scope – **Marci Layton, CSTE**<br>• Will transition this call to a monthly cadence<br>• Will likely cancel June meeting as there were 3 meetings in May and the meeting will fall on the week of the CSTE annual conference. If active issues, can move to another time in June for an ad hoc meeting.<br>• Will plan to restart meetings in July on the third Tuesday of the month, 2-3pm.<br>• Plan to expand beyond COVID-19 to other infectious diseases<br>• Continue to serve as a forum for APHL, CSTE, and CDC to obtain guidance and feedback from Thought Leaders in Lab/Epi<br>• Plan to keep monthly meetings on the calendar, however, only hold meetings if there are active issues to discuss. |

## Action Items

[From last meetings, until closed]

| # | Activities/Deliverables | Action Item/Responsible | Due Date | Status |
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| 1 | Performance of diagnostic tests for known SARS-CoV-2 Variants and Plans for Optimization of Diagnostics for Future Emerging Variants | ☐ Will add this topic to a future meeting once more data is available for public health action | June-July | Pending |

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| 2 | CSTE AMD Workgroup and Webinar Series | **Please complete the interest form via the link provided HERE if you would like to participate in the CSTE AMD Workgroup.**<br>**CSTE AMD webinar Registration Link for the webinar: "Problem-solving Collaboration Between Laboratory and Epidemiology Programs on COVID-19" on Wednesday, June 8, 2022 at 4:00 pm EDT** | 6/10/22 | Pending |
| 3 | APHL SARS-CoV-2 Genomic Surveillance Document | **The document is available on the APHL website to members. Additionally, after the call Kelly will share the open link for those who are not APHL members.**<br>**Questions re: the recommendations: David Wentworth email: dwentworth@cdc.gov** | 6/10/22 | Pending |
| 4 | OpET and ICATT Data Dashboards | **Would like feedback from STLTs to enhance STLT usefulness: eocevent588@cdc.gov** | 6/10/22 | Pending |
| 5 | Next CSTE/APHL/CDC Infectious Diseases Lab/Epi Thought Leaders Meeting | Will cancel June meeting, unless an ad hoc meeting is needed for active issues.<br>Then, starting in July, monthly meetings scheduled, the third Tuesday of every month 2-3PM, when active issues. Updated calendar invite coming. | July | Pending |