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CSTE-CDC COVID-19 Core Epi Workgroup Meeting:

Date:	**Wednesday December 7, 2022**
Start/End Time:	1:30-2:30p

CSTE-CDC Core Epi COVID-19 WG Notes and Action Items

#	Topic	Items
1.	Introductions	**Open and Welcome – Ben Chan, NH**
2.	Feedback on FDA Center for Devices & Radiologic Health Response to COVID-19	**Feedback on FDA Center for Devices & Radiologic Health Response to COVID-19 – Tim Stenzel, FDA** • Purpose is to get feedback on the FDA responses to COVID-19, Mpox, and now Ebola as well • Reaching out to other organizations as well, including APHL • Want feedback on successes and lessons learned and what can be done better and potential solutions for future PHEs • They have made adaptations to processes over the COVID-19 pandemic response • FDA used EUA authority for several other situations before COVID-19. It allows the FDA to lower the validation efforts, with less requirements, but still requires validation to ensure accurate tests. Prior to the COVID-19 response had developed EUA templates, for how many positives, how many negatives, for validation, etc., for a test. Designed to be used and inputted and sent back to FDA, for an all-in-one simple streamlined approach in a PHE. Used with Zika, Ebola, and others. • In January 2020, worked with the CDC, made the EUA templates available in Jan. 2020, a revised template for COVID-19. It was for kit developers, academic labs, clinical labs. Less for PHLs, bc PHLs had CDC test. But while the FDA EUA templates were available and distributed in January 2020, only had one in early Feb and one (Wadsworth) in late February. • FDA wanted a faster pace of submissions, therefore, let labs know they could submit their data three weeks later, if lab validated. • Mid-March made some other adjustments • Enforcement discretion for LDTs • Over 6-8 weeks, CDC assay to many labs able to perform with their own LDT or a kit, of which there were 40M by the beginning of March • In the beginning allowed mock samples, because there were very limited sample availability, with 30 positive and 30 negative samples • Then, in mid-March realized serology was unlikely to be helpful and decided if validated by the manufacturer and they didn't make unfounded claims, they only had to notify FDA. • Within 4-6 weeks, heard that the many serology tests were not performing well. So, reversed that allowance and required to be tested against bank serology samples, positive and negatives, and many failed, and were removed from the market. Also, complicated by the fact that they were being used for intentions not allowed at the time (going back to work) • Mpox: Allowed academic research centers to develop Mpox tests, didn't want to hold them up.

		• Then, transitioned away from the mock samples contrived samples to actual patient samples • Over the COVID pandemic, FDA added antigen test templates, home test templates, home collection, serology templates, POC templates • Ended up with over 6,000 test developers submitted to FDA. All submitters were treated equally. Vast majority were kit manufacturers, next commercial, then academic, smallest group was PHLs (because we had a test that CDC provided to PHLs. Wadsworth submitted to FDA, copied the CDC design, and submitted the validation directly to FDA and was authorized within one day, because CDC test had flaws). • Attached in email from Andrew are the latest revisions to the EUA templates, revised with lessons learned from COVID response. • Also, an abbreviated version was provided based on feedback for Mpox that it was still too long. • During COVID, reviewed more tests than during any other time in FDA history (PHE or not) • **Discussion:** o Appreciated all the work FDA did during the COVID-19 response o Appreciated prompt FDA turnaround after submission of test validations during the COVID-19 response, once submitted was very quick turnaround time o Would be great to have re-evaluation once real specimens are available (after approval with contrived sample) o Pathogen X: Can FDA work with CDC and other partners and PHLs to work on these top listed pathogens developed by WHO, CDC, etc, for potential Pathogen X? For example, Sudan virus was on the list previously, to develop the tests in advance and be more prepared ▪ FDA remarked that 564 declaration is different than a PHE declaration ▪ PHE will end soon for Mpox - but need these EUA ▪ Current flexibility works well o FDA notes that every PHE is different o Also, FDA notes that labs can submit a Pre-EUA and FDA was encouraging this for Mpox o FDA would like universal EUA templates and some specific for various types of pathogens: Bloodborne pathogen, fecal pathogen, skin lesions, resp pathogen standardized templates for EUAs. o FDA wants feedback on right sizing the number of specimens to be reviewed during a PHE and the process – balancing ensuring accuracy of test versus rapidity of availability of testing • **Member feedback:** o Don't see this as a static number of specimens that should be reviewed, as early on it may be different than later. This should change over time. o Early antigen test companies were reporting very high specificity, that didn't bear out over time or in real world settings and varied by asymptomatic versus symptomatic, so the test validation approach needs to evolve over the pandemic and need methods for FDA to work with STLT HDs to understand the real world use data. o Is there thought to having an isolate bank or specimen bank for when there is a PHE or outbreak that is evolving so that test manufacturers have access to additional specimens for validation

		• Throughout medical device reporting (MDR), FDA has been monitoring throughout the pandemic, to evaluate if there is an uptick in the false negatives or false positives. If so, they would ask for more data
		  ○ Such as with the Abbott IDNow
		  ○ They recognize that some of the sensitivity and specificity early on were very high, such as 97%, and it was unexpected. Some reasons could be:
		  ▪ 30 samples is small, so could lead to variability
		  ▪ Didn't have asymptomatic data, where sensitivity is lower
		  ▪ Why all FDA labeling was a 'presumed', so a negative was a presumed negative.
		  ▪ If the companies perform all of the validation, FDA doesn't know if they selected results. FDA does go over things with fine tooth comb and try to spot certain types of deception, but can't oversee it.
		  ▪ ICATT – NIH took over the entire validation of the tests, which improved confidence in the data coming in and how test performed
		  • Independent trusted data
		  • More real world data
		  ▪ Recommend an independent assessment entity moving forward for test validations
		• Discussion - What happens next?
		  ○ What is the next step for all these tests that are under EUA
		  ▪ FDA: There is a process for full authorization, which would require more positives and a lot more negatives
		  ○ Question: Salivary Mpox testing in California:
		  ▪ FDA was alerted to it, but had limited authority because of enforcement discretion for LDTs.
		  ▪ Need legislation to solve this issue, and enable authority to obtain data
		  ▪ FDA did put out a safety communication re: non-lesion samples
		  ▪ For non-lesions swabs, wanted submissions to FDA for validation

5.	Future Topics	**Future Call Topics and Tentative Agendas** Changes to Upcoming Calls: • **Dec 14th: CDC COVID-19 Surveillance Framework** (*Canceled Dec. 21st due to holidays*) • **Moving call from January 4th to January 11th** • Will hold two calls in January and then reassess ongoing workgroup needs based on the status of the pandemic

Action Items

#	Activities/ Deliverables	Action Item/Responsible	Due Date	Status
1.	**Comments or feedback for FDA**	☐ **Email Andrew Adams (aadams@cste.org) or Marci Layton (mlayton@cste.org) with any feedback or comments for FDA**		Pending

Next Meeting – Next Week: Wednesday December 14th 2022, 1:00-2:00PM Eastern Time
(*canceled December 21st due to the holidays*)