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CSTE/APHL/CDC COVID-19/Infectious Diseases Lab/Epi Thought Leaders Workgroup Meeting Notes and Action Items

Date:	**Tuesday August 23rd, 2022**
Start/End Time:	**2-3PM ET**

#	Topic	Items

1.	Open and welcome	**Open and Welcome – Sherri Davidson (AL) and Tim Southern (SD)**
		• Introductions
		• Background for reference
		  ○ FDA Safety Communication: 'At-Home COVID-19 Antigen Tests - Take Steps to Reduce Your Risk of False Negative' (*August 11, 2022*)
		  ○ FDA/NIH/UMASS collaborated on a study, pre-print in MedRxiv: Performance of Screening for SARS-CoV-2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort
		  ○ CDC's COVID-19 Testing: What You Need to Know (*updated August 11, 2022*)

2.	At-home OTC Antigen Testing Sensitivity and CDC Communication Messaging	**At-home OTC Antigen Testing Sensitivity and CDC Communication Messaging – Ian Williams (CDC), Ren Salerno (CDC), and Tim Stenzel (FDA)**
		• FDA safety communication ~10 days ago, based on the publication with link above and summarized below.
		  ○ Currently, ~19 OTC rapid antigen tests authorized by FDA
		  ○ Through the end of 2021, expected performance of rapid antigen tests on symptomatic patients was approximately sensitivity of 80% or more with high specificity (the bar was set at 80% or higher with one test for sensitivity in symptomatic patients)
		  ○ Serial testing was recommended in asymptomatic patients based on U. of Illinois data on serial testing in asymptotic patients for those tests that had adequate testing on symptomatic pts but did not have adequate data on asymptomatic.
		  ○ FDA and NIH discussed doing a large asymptomatic screening study with home rapid antigen tests and worked with UMASS to perform the study. Pts signed up for a two week period while asymptomatic and did a rapid test every other day. Some became symptomatic. Enrolled more than 7,000 patients. Identified performance in both asymptomatic and symptomatic pts, during the Omicron era. Serial testing was required to get adequate sensitivity.
		  ○ Two tests improved the symptomatic performance and three tests improved the asymptomatic performance – to rise above 80% sensitivity
		• ~10 days ago, CDC updated guidance for community and schools and this guidance references the FDA website.
		  ○ Updated guidance on high risk congregate settings (including for those persons experiencing homelessness and correctional settings), healthcare settings, and travel are pending. CDC website pages currently being updated.
		  ○ Streamlining and trying to make webpages as evergreen as possible and consistent between CDC and FDA.
		• Discussed why this discussion matters: concern raised re: ongoing spread of COVID-19 and ongoing deaths, that are important to try to prevent.
		• Discussed moving forward, for those who might be immunocompromised and less responsive to the vaccine, the important communication point is to know when you have disease early (i.e., test early and treat early. How do these findings impact that approach?

- FDA is updating package inserts/labeling.
  - Noted that the public don't usually read these.
- CDC updates are in process.
- Discussion re: how it is hard to get people to do one test, therefore 2 or 3 serial tests would be quite challenging and potentially cost prohibitive.
- Discussed messaging on rapid antigen testing
  - Sensitivity for symptomatic and asymptomatic persons
  - Recommended serial testing
  - The reason for serial testing compared to earlier in the pandemic
  - Recommendation for behavior modification during the time of negative test
  - For symptomatic pts, if the sensitivity is also low, it should be very clear that they 'should stay home and not expose other people.'
- Discussed the need to clarify who is being targeted by this messaging.
  - For instance, for a symptomatic child to return to school, what do they do with this information? They would be out of school for a week if they needed to test negative 2-3 times. So, we need to clarify where this information should be used and where it shouldn't be used.
- Discuss the use of at-home OTC rapid antigen tests as markers of infectiousness
  - What are the most recent data on rapid testing use for infectiousness?
  - What is the current CDC messaging re: infectiousness for the public and HCPs
  - How do we strengthen discussion on different uses of rapid tests (diagnostic and infectiousness) and the data behind accuracy for each purpose?
  - If you are still antigen test positive, you are likely to still be infectious, there is good correlation between antigen test positivity and culture test positivity. But, the reverse may not be true. And some people are persistently positive out to 8, 12, 14 days, not common, but seen.
  - Discussed messaging surrounding evaluating for asymptomatic infection when concerned about infectiousness, to consider not doing one test before an event, rather need to consider doing three tests before an event or spending time with a high risk individual, then your chances of having COVID-19 and giving it to someone are very low. This example can help get the message out about how to use these tests with an emphasis on how low the single test sensitivity is among asymptomatic infected people (it is in the range of 20-30%, so you are missing 70-80%), so 'need to test three times in a row'.
- Discussed the use of rapid antigen tests as a marker of infectiousness once infected
  - What is the messaging around the 5-day isolation and 10-day wear a mask guidance and what to do if someone continues to test positive by antigen
  - Discussed need to address testing options to remove masking.
  - Discussed trying to strike a balance. If need serial testing to test out of isolation, that can be an equity issue.
- Discussed how do we approach mechanisms of communication re: HCPs and the public to get the right message out about test to treat and use for infectiousness.
- Discussed these findings are not surprising as the population has more immunity, the antigen tests, particularly the negative result, become less reliable. Though there is value in the positive result. This is a challenging message to share and understand.
- CDC is recommending that screening testing is not useful in most settings in the community, with some exceptions around high-risk congregate settings, current and updated guidance is de-emphasizing asymptomatic screening.
- Question raised re: plans or schedules to revalidate assays as strains change?

		○ FDA for many years for flu requires verifying performance for strains of flu. Expect the same. • The shift between Delta and Omicron predominating, in a matter of weeks, coincided with a dramatic drop in performance of rapid antigen tests. That is when recommendations began for serial tests for symptomatic pts. This suggests that the virus can change the antigen test performance, and there might be some combination of how much virus is being shed and at what body sites. This change seemed to occur before *everyone* got Omicron (suggesting it was not related to immunity, rather different variants). • A safety communication went out in Nov or Dec of 2021 re: reduced sensitivity. • Discussed where are we moving with our messaging? ○ Trying to differentiate exposed and infected paths. ○ Symptomatic, asymptomatic, and high risk setting screenings. ○ Loosening recommendations around screening for antigen testing for asymptomatic individuals. • Discussed the results and implications of the Soni et al. pre-print: ○ What are the implications for use of antigen tests for screening, particularly in high-risk congregate settings (like LTCFs) ○ Data from the pre-print, when compared to PCR, even with serial testing, for asymptomatic, still poorer sensitivity. ○ LTCF testing recommendations are important or LTCFs to use molecular testing. ○ There have been multiple studies over the last >1.5 years, back to even in Dec 2020 and Jan 2021, showing that single test sensitivity was very low, 20-40% among asymptomatic persons. This is why some STLTs have advocated against routine screening in LTCFs for asymptomatic screening. • Discussions between CDC, CMS, and OSHA to try to strike a balance for the most vulnerable citizens. This messaging may influence CMS requirements. • CDC to strengthen and simplify messaging.

NEXT MEETING
Tuesday September 27th, 2022 2-3PM ET