Antigen testing for SARS-CoV-2

- Testing of asymptomatic SNF residents in non-outbreak settings:
  - CDC recommends that testing of asymptomatic nursing home residents be reserved for situations such as response to an outbreak in the facility (i.e., a new SARS-CoV-2 infection in any healthcare personnel (HCP) or any SARS-CoV-2 infection in a resident) or evaluation of a resident who has had close contact with someone with confirmed SARS-CoV-2 infection.
  - Regular testing of asymptomatic residents can result in false-positive results and potentially result in additional unnecessary testing.
- When should an antigen test be considered a false positive?
  - A point-of-care test should be considered a possible false-positive when a positive test result appears inconsistent with the clinical situation (e.g., a positive antigen test in an asymptomatic person who does not have risk factors and resides in a community with lower COVID-19 prevalence).
  - Consider the pre-test probability of disease (based on presence of symptoms, exposure to known cases, prevalence).
    - If testing a population with a COVID-19 prevalence >10% (e.g., testing asymptomatic residents and HCP as part of an outbreak response) with a test specificity of 99%, the positive predictive value (probability that a positive test is a true-positive) may be >90%.
• If testing a population with a COVID-19 prevalence <1% (e.g., screening asymptomatic HCP in non-outbreak settings) with a test specificity of 99%, the positive predictive value may be <40%.
• Therefore, testing in low-prevalence populations with antigen (or RT-PCR) tests might produce false positives, but that is less likely in outbreak settings (higher prevalence).
  o Compare the percent positivity of the samples that were run that day (or week) to their previous percent positivity (e.g., their rolling 7-day average percent positive). Identifying many positives in one day might indicate an issue with the antigen results (either due to operator error or test supplies).
  o Review recent control results to ensure accuracy of the antigen test machine. If able, perform procedural quality control tests to ensure correct operation of the machine.
• Confirmatory testing recommendations (from CDC)
  o Note that confirmatory RT-PCR testing after a positive antigen test result is not recommended in situations where the person being tested has COVID-19–like symptoms or had recent close contact with someone with SARS-CoV-2 infection (e.g., in an outbreak situation).
  o When a confirmatory test is pursued, optimize the performance of the confirmatory test by doing the following:
    ▪ Use real time RT-PCR as the confirmatory test.
    ▪ Nasopharyngeal (NP) swabs used correctly have a higher sensitivity than other specimen sources. Therefore, confirmatory tests should be performed using NP swabs.
    ▪ If the person is unable to tolerate a NP swab, then a swab of the anterior nares or mid-turbinate could be considered as these specimen types may have similar or slightly less sensitivity but may be more tolerable.
    ▪ Perform the confirmatory test within 2 days of the initial test. Tests performed >2 days apart should be considered separate tests, and discordant results may be due to changes in viral dynamics.
• Discordant results: Antigen test is positive and confirmatory RT-PCR is negative
  o If individual is symptomatic and from an outbreak situation: consider as infectious (although confirmatory testing not recommended in these circumstances).
  o If individual is asymptomatic and not from an outbreak situation: consider as negative
    ▪ Individual should continue to be monitored for symptoms. If an asymptomatic person with discordant test results begins to exhibit COVID-19–like symptoms in the subsequent week after testing, that person should be considered to have COVID-19. Repeat testing is not recommended in this situation.
• If the person is asymptomatic and is not a known contact or part of a facility response to an outbreak, then the discordant test results could indicate a false-positive antigen test result. In this situation (particularly in lower prevalence areas), it is reasonable to continue symptom screening and test residents and HCP with COVID-19–like symptoms, and not institute the control interventions (e.g., facility-wide testing, excluding HCP with discordant results from work, moving resident with discordant results to a COVID-19 unit).
If discordant test results suggestive of a false positive antigen test are identified, facilities and health departments should notify the test manufacturer and the FDA.

**Antigen tests for SARS-CoV-2**
1) Quidel Sofia SARS Antigen FIA assay (within 5 days of onset); Influenza A/B test kit available
2) BD Veritor System for Rapid Detection of SARS-CoV-2 (within 5 days of onset); Influenza A/B test kit available
3) Abbott BinaxNOW COVID-19 Ag CARD (within 7 days of onset); Influenza A/B test kit available but requires reader
4) LumiraDx SARS-CoV-2 Antigen Test (within 12 days of onset)

### IV. Healthcare-Associated Infections: Dr. Erin Epson

Yesterday CDPH HAI program posted updated guidance for the prevention and control of influenza in skilled nursing facilities during the COVID pandemic; this guidance will also be distributed via an All Facilities Letter. SNF residents are at increased risk for severe disease, hospitalization, and death from infections caused by influenza viruses and SARS-CoV-2. The ongoing COVID-19 pandemic and the potential for concurrent COVID-19 and influenza outbreaks will complicate the upcoming influenza season; therefore, it is essential for SNFs to optimize all available effective influenza prevention and outbreak control interventions, including influenza vaccination of SNF residents and healthcare personnel (HCP) and prompt initiation of antiviral therapy and chemoprophylaxis when influenza is identified. In addition, the overlap of clinical presentations and contribution of asymptomatic transmission of SARS-CoV-2 makes it difficult to manage residents based on symptoms alone. Each SNF must therefore develop plans for: testing symptomatic residents for both influenza and SARS-CoV-2; implementation of transmission-based precautions; determining resident room placement while avoiding movement of residents between COVID-19 cohorts; and prompt initiation of influenza antiviral agents therapeutically and prophylactically when an influenza outbreak is identified in a facility.

Regarding the timing of influenza vaccination relative to an individual’s COVID status for individuals already in a healthcare setting, such as SNF or hospitals, we understand that CDC will be releasing their guidance soon. As with other vaccines, mild illness is not a contraindication to influenza vaccination. Healthcare providers can vaccinate SNF residents or clinically stable hospitalized inpatients nearing discharge who have mild illness or those who are quarantined following a SARS-CoV-2 exposure, but should be aware that post-vaccination symptoms such as fever or myalgia could create diagnostic confusion and necessitate evaluation for COVID.

### V. Remdesivir Update Dr. Philip Peters

**Remdesivir Distribution and General Therapeutic Update for all Healthcare Facility Call**
As of October 1st, the directed allocations of remdesivir have ended. As the supply greatly exceeds the demand for remdesivir nationally, hospitals can now purchase unrestricted amounts of remdesivir directly from the distributor, AmerisourceBergen, which will remain the sole distributor of remdesivir until at least December 2020. The EUA conditions for use remain the same and we will continue to monitor for changes to the EUA. AmerisourceBergen is available to answer questions or concerns from
purchasing hospitals and you can also reach out to us at CDPH if you are having issues. Contact information for Amerisource Bergen is included in the notes:

AmerisourceBergen can be contacted directly at 877-746-6273 or via email at remdesivir@amerisourcebergen.com.

A weblink is posted on the CDPH guidance page in the “other” section with the final remdesivir distribution details.


As a reminder that the California Medical Association in collaboration with CDPH will be hosting a virtual grand rounds on October 13th at noon. The topic will be COVID-19 treatment and will feature an excellent speaker who will discuss cutting edge issues relevant to clinical providers. You can find more information on the CMA website and I’ve included a link in the notes as well:


VI. Questions and Answers

Q: Will the AFL being released with updated visitor guidance and when will it be released?
A: Per Heidi, Yes, we will have two separate visitation guidance that are currently undergoing stakeholder review. We do anticipate being able to use the tier system that we know as the color guide purple, red, and orange.

Q: The CDPH website shows less than 11 deaths, but we’ve had no deaths.
A: Per Heidi, thank you for that if you do see that then let us know. We recently went through and re-did the website and you’ll see the numbers suppressed as less than 11, but if you reach out to me offline, we can address that.

Q: With the CDC releasing their guidelines yesterday around airborne infections of COVID are you going to be looking at changing precautions around isolation?
A: Per Dr. Erin Epson, we are not changing our infection control recommendations based on that updated information from CDC. I’ll make a clarification the recommendation for COVID is use of n-95 or higher level that protects against smaller particles and aerosols. For healthcare personnel working with patient at close range we recommend the use of an approved N-95 or better. What CDC described as airborne as in long distance or potential for these particles these aerosols to be suspended in the air for prolonged periods.

Q: On-site antigen testing devices, as a non-CMS facility, we will not get the devices or the supplies. Is CDPH looking at non-CMS SNF facilities and what are they doing about it? For grants that are being provided for partitions and tents, Will facilities that are not a part of CMS licensing be included in that grant. Is that a state grant or federal grant?
A: Per Dr. Jacobson, to answer your first questions, one of the locations of distribution is congregate settings and for those facilities that have not any allocation from federal government I would recommend reaching out to your MHOAC program. Per Heidi S., for the CMP funds you can apply, and we do have information about that on our website with an email address of where to get more information for grants.

Q: Is the Battelle system no longer in use or accepted?
A: Per Dr. Epson, that’s correct as per Cal OSHA guideline issued in early August, they are no longer accepting the use of disinfected N-95 respirators.

Q: Binax Now testing. Does each facility need to apply for these?
A: Per CDPH, the state will allocate two counties based on the first round that would be based on population and case per hundred thousand. You would reach out to the county via the MHOAC system.

Q: Can you please explain how the MHOAC program would apply for the Binax Now machines?
A: Per Phil, for the county that the facility is in is to reach out to the county LHJ health department. Each county is structured differently. It’s someone who works in the County operations, please reach out to the MHOAC program. We do have a list for each MHOAC and we could put you in touch with the right person. I’m not sure how it will work for the tests, but how it worked for Remdesivir was hospitals utilized their existing mechanisms and were able to prioritize the need of Remdesivir based on volume, etc. It took a few weeks for things to get moving smoothly, but our goal is to make everything transparent. Therefore, you will need to reach out to your LHJ.

Q: In relation to AF 20-75, which outlines the expectations for outbreak thresholds and recording, we’re having confusion on how to define epi linkage with workers that are testing positive and upon further review we found that they used PPE properly but independent of work experience may have been exposed. What is the Epi Linkage for that?
A: Per Dr. Epson, we recommend investigating and potentially reporting to public health even when PPE was supposedly in use, because of the concern that despite policy and procedures in place adherence to facemasks is not always complete. The cases that meet a threshold really are a signal of a break down or lapse in source control that should be investigated further.