California Department of Public Health
Weekly Facility COVID-19 Update Call
December 8, 2020
8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041
Access Code: 2726567
Available after 10am 12/08/2020

I. **Welcome / Introduction** — **Heidi Steinecker**

II. **Overview** — **Dr. Kathleen Jacobson**

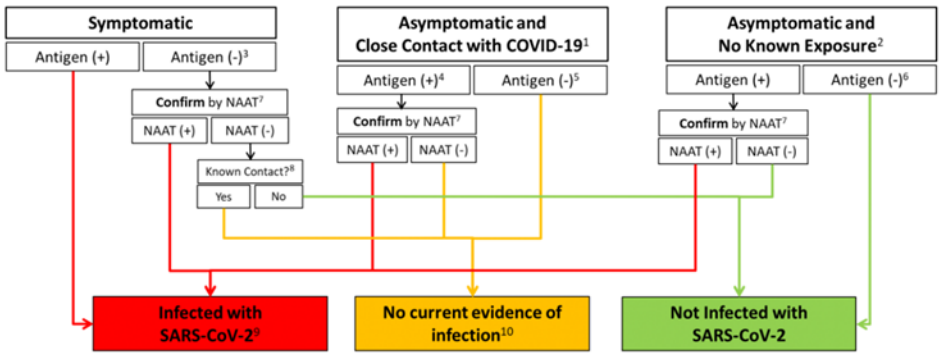
- None Provided

III. **Laboratory Update** — **Dr. Deb Wadford**

CDC issues updated Antigen testing guidance for SARS-CoV-2
https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

This update contains extensive information about antigen testing for SARS-CoV-2. Please refer to the website for details, including 1) general guidance, 2) regulatory requirements, 3) analytical performance, 4) tips for processing antigen tests and evaluating the results based on lessons learned in the field and from studies, 5) reporting antigen test results, and also included, 6) an antigen testing algorithm based on the presence or absence of symptoms and pre-test probability of infection; recommended confirmatory testing scenarios are included in the algorithm.

Figure 1. Antigen Test Algorithm



Of note: Persons performing the antigen test must be properly trained per the manufacturer's instructions including proper tempering of the test kit to room temperature, with strict adherence to specimen type collected, immediate testing of the specimen, and proper reading of the test result. Most erroneous test results are due to improper use of the test.

Antigen tests can be used for screening testing in high-risk congregate settings in which repeat testing could quickly identify persons with a SARS-CoV-2 infection to inform infection prevention and control measures, thus preventing transmission. In this case, and especially in settings where a rapid test turnaround time is required, there is value in providing immediate results with antigen tests, even though they may have lower sensitivity than nucleic acid amplification tests or NAATs. Additionally, both diagnostic testing results and screening testing results (positive and negative) must be reported to the local, state, tribal, or territory health department in accordance with state, federal, and local regulations and with the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act).

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***Serial testing when using antigen tests*:**

Depending on the circumstances and setting, it may be useful to implement serial antigen testing for persons who receive a negative antigen test result. Serial antigen testing within a closed congregate setting, such as a long-term care facility or a correctional or detention facility, could quickly identify someone with a SARS-CoV-2 infection and prevent further transmission. It may not be necessary to perform confirmatory testing with a NAAT when conducting serial antigen testing on those who have received a negative antigen test result. Serial testing, particularly in congregate settings when it has been possible to quarantine persons for 14 days, should not continue indefinitely.

Modeling evidence shows that outbreak control depends largely on the frequency of testing, the speed of reporting, and the application of interventions, and is only marginally improved by the sensitivity of the test.

See CDC's Overview of Testing for SARS-CoV-2, https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html, and FDA's FAQs on Testing for SARS-CoV-2

Point of Care Antigen tests for SARS-CoV-2 with FDA EUA:

1. Quidel Sofia SARS Antigen FIA assay (test within 5 days of onset)
2. Quidel Sofia 2 Flu + SARS Antigen FIA assay (within 5 days of onset)
3. BD Veritor System for Rapid Detection of SARS-CoV-2 (within 5 days of onset)
4. Abbott BinaxNOW COVID-19 Ag CARD (within 7 days of onset)
5. LumiraDx SARS-CoV-2 Antigen Test (within 12 days of onset)
6. CareStart™ COVID-19 Antigen (within 5 days of onset)

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen

Q&A Follow up:

Question from Q&A period regarding use of an antigen test that has received FDA Emergency Use Notification (EUN) but not Emergency use Authorization (EUA). The information below is from the FDA website:

> *Test kits on a notification list that are not identified as "Authorized" have not yet been reviewed by the FDA, are not FDA authorized, and have not received a CLIA categorization. Unless and until an EUA is issued that authorizes additional testing environments for a specific test, under CLIA, use of that test is limited to laboratories certified to perform high complexity testing, and at the point-of-care when covered by the laboratory's CLIA certificate for high-complexity testing.*
>
> *Laboratories offering such tests may be subject to additional requirements regarding establishment of performance specifications under the CLIA Regulations. Laboratories with questions about these requirements should contact CMS at LabExcellence@cms.hhs.gov*

The information from the FDA above indicates that a test with EUN should not be used and that only tests with an FDA EUA are approved for diagnostic or screening testing.

IV. **Healthcare-Associated Infections** **Dr. Erin Epson**

1. CDPH developed a FAQ document with additional information and clarifications regarding AFL 20-88 Coronavirus Disease 2019 (COVID-19) Testing Recommendations for Patients and Health Care Personnel (HCP) at General Acute Care Hospitals (GACHs).

Which items in AFL 20-88 are requirements and which are recommendations?

Hospitals are required to submit a General Acute Care Hospital COVID-19 Mitigation Testing Plan (PDF) that details a plan for weekly testing of HCP to their local CDPH licensing district office by December 14 for review. The facility's tracking plan for testing should include documentation of those who test positive, negative and those that decline testing.

CDPH strongly **recommends** the mitigation testing plan elements detailed in the AFL, including:

- Implementation of weekly screening testing of all HCP by December 14
- Initial prioritization of HCP in high-risk categories for testing while the hospital develops testing capacity and procedures
- Immediate testing of symptomatic HCP rather than delaying testing until scheduled screening
- No routine retesting of asymptomatic HCP who have had a positive viral test in the prior three months
- Consideration of retesting, in consultation with infectious disease or infection control experts, for any HCP with a positive test in the past three months if they become newly symptomatic without identifiable alternative etiology
- Policies and procedures that address the use and follow-up of test results

- Testing newly admitted and recently exposed patients, including patients exposed while hospitalized or who develop new symptoms potentially consistent with COVID-19 during their hospitalization
- Policies and procedures for work exclusion of positive HCP informed by Centers for Disease Control and Prevention (CDC) guidance
- Use of authorized SARS-CoV-2 virus nucleic acid tests for symptomatic or asymptomatic individuals or an antigen detection assay for symptomatic individuals
- Consideration of the use of labs that perform pooled testing for routine weekly screening of asymptomatic HCP

Even if the facility opts to not implement weekly testing, the facility must still submit a mitigation testing plan.

For questions about a facility's particular plan, the facility should work with their local CDPH district office and local health department for technical assistance with regard to the facility's specific testing capacity, staffing, patients, and community.

Is the definition of HCP and the related testing recommendations limited to personnel who work in clinical areas where patient care is delivered?

CDPH uses the CDC's standardized definition of HCP, which refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

For the purposes of a screening testing program for HCP, hospitals should prioritize HCP working in or likely to interact with other HCP who work in patient care areas; hospitals may opt to not include purely administrative personnel in their testing program, especially those working in separate administrative offices or buildings

How can hospitals obtain the necessary testing supplies, given supply shortages?

The testing recommendations in AFL 20-88 are predicated on adequate testing capacity; where testing capacity is limited, routine screening testing of hospital HCP should not compete with higher priority testing needs, such as for symptomatic patients. Hospitals should communicate their testing capacity limitations and shortages to the California Testing Task Force (testing.taskforce@state.ca.gov).

Facilities have encountered difficulty obtaining testing reagents for multiple platforms and submitting to national testing labs that limit specimen submission. Some testing platforms are proprietary and will

not allow outside supplies to be used. Open platforms do exist, including the CDPH Valencia Branch laboratory that uses open platform PerkinElmer equipment and where supplies can be obtained for use on multiple other open platforms.

The State of California plans to continue to engage in partnerships with multiple laboratories to ensure the state diversifies its testing capabilities. The CDPH Valencia Branch Lab was opened with the intention of increasing the state's COVID-19 testing capacity and reducing test turnaround time. Upon reaching full capacity early in 2021, this lab will add 150,000 tests to the state's overall testing capacity, with the expected per-test cost approximately one-fifth to one-sixth the current average cost.

The Testing Task Force website provides relevant resources including, but not limited to, lab resources for testing, guidance on pooled testing, and information on the state's supply distribution.

Hospitals that are unable to obtain adequate testing materials may submit a resource request for any supplies to their Medical and Health Operational Area Coordinator (MHOAC) through the Salesforce platform, ReddiNet platform, or another locally established process. Although the California state stockpile does not have viral nucleic acid test kits at this time, sample collection supplies (swabs and media) and BinaxNOW rapid test cards for antigen testing are available.

Can hospitals use the CDPH Valencia Branch Laboratory for testing? If so, what are the processes for obtaining supplies, sending in specimens, etc.?

The Valencia lab has contracted with PerkinElmer to utilize PCR diagnostic testing. The Testing Task Force website provides additional information on this lab, including a detailed playbook with preliminary information for organizations seeking to partner with the lab to become a community-based collection site.

V. **Remdesivir Update** **Dr. Philip Peters**

To summarize, two investigational monoclonal antibody products have received an emergency use authorization (EUA) for the treatment of mild-to-moderate COVID-19 in non-hospitalized adult and pediatric patients. Bamlanivimab received an EUA on November 9th and is a single monoclonal antibody. Casirivimab/imdevimab received an EUA on November 21st and is a cocktail of two monoclonal antibodies. Clinical trial data in outpatients have shown that both bamlanivimab and casirivimab/imdevimab may reduce COVID-19-related hospitalization or emergency room visits in patients who are treated early and who are at high risk for severe disease. Clinical trial data in hospitalized patients, however, have not shown a benefit with either bamlanivimab or casirivimab/imdevimab use in hospitalized patients and as such the EUAs for both therapies is only to treat symptomatic outpatients. Finally, bamlanivimab is less complex to prepare for infusion than casirivimab/imdevimab and CDPH is looking at appropriate non-hospital outpatient settings to provide access to this medication. As casirivimab/imdevimab is more complex to prepare, we are currently only distributing via acute care hospital infusion settings.

Bamlanivimab updates

For week four, California received an allocation of 3,790 doses.

Starting in week four, CDPH allocated 750 doses of bamlanivimab to 8 large specialty pharmacies that provide medications to 80 – 90% of skilled nursing facilities (SNFs) and PACE programs in California. Medical directors or other authorized prescribers at SNFs and PACE programs who contract with these pharmacies can order bamlanivimab if they have a patient that qualifies for treatment. The pharmacy would prepare the product for infusion and send to the SNF or PACE program for infusion. The 8 pharmacies for this distribution of bamlanivimab are Pacific West Pharmacy, Skilled Nursing Pharmacy, Consonus Pharmacy Services, AlixaRx, Pharmerica, Citrus Pharmacy, Ron's Pharmacy, and OmniCare.

The remaining 3,040 doses of bamlanivimab that were not distributed to these specialty pharmacies were proportionally allocated to the counties' Medical and Health Operational Area Coordinators (MHOACs) based on their 7-day average of new COVID-19 hospitalization and 7-day average of overall new COVID-19 diagnoses.

Details on the allocations are here:
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CA-Monoclonal-Allocation-11-27-20.xlsx

To date most of the allocation of bamlanivimab has gone to clinical sites affiliated with acute care hospitals because of the existing infrastructure to infuse an outpatient medication but CDPH is encouraging counties consider allocating bamlanivimab to more outpatient settings including federally qualified health centers (FQHCs), state hospitals, jails, and other congregate setting that may have clinical capacity to use.

Casirivimab / imdevimab updates

California received an allocation of 2,160 doses of casirivimab / imdevimab this week. The same formula is used to proportionately distribute casirivimab / imdevimab to the counties' MHOACs. The MHOACs then allocates casirivimab / imdevimab within their county. Initially the plan is to other allocate to acute care hospitals and their affiliated settings as casirivimab / imdevimab is more complex to prepare. The casirivimab / imdevimab product is also not well labelled and is prepared in two different doses which adds complexity for the pharmacy

Grand Rounds

Finally, I want to draw your attention to an exciting upcoming grand rounds cosponsored by CMA and CDPH on Tuesday, December 8th at noon. The topic is "The National COVID-19 Surge and Hope for 2021 - A Conversation with State Leaders and Members of President-Elect Joe Biden's Coronavirus Task Force". The grand rounds will include a conversation with Dr. Robert Rodriguez and Dr. Eric Goosby who are two physicians that hold central roles on President-Elect Joe Biden's Coronavirus Task Force as well as Dr. Seema Jain from CDPH who is an expert in the epidemiology of winter respiratory viruses and will discuss an approach to viral co-infections with COVID-19.

Link: https://www.cmadocs.org/event-info/sessionaltcd/CME20_1208_GRCOVID

Additional Resources

Bamlanivimab links for further information:
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Bamlanivimab-Fact-Sheet.aspx

Fact sheet for healthcare providers: https://www.fda.gov/media/143603/download

Casirivimab / Imdevimab links to the EUA including information for healthcare providers and patients is included in the meeting notes.

FAQ: https://www.fda.gov/media/143894/download

Fact sheet for health care providers: https://www.fda.gov/media/143892/download

Fact sheet for patients, parents, and caregivers: https://www.fda.gov/media/143893/download

NIH COVID-19 Treatment Guidelines: https://www.covid19treatmentguidelines.nih.gov/whats-new/

IDSA COVID-19 Treatment Guidelines: https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/#toc-10

VI. Questions and Answers

Q: One question, is there going to be an AFL this week accepting CDC recommendation to reduce quarantine time for HC Personnel
A: Heidi: For updating guidance around quarantine time, our policy team will be looking at all our ALFs to see what needs to be updated. Sometimes what we do is put the link to CDC so that it auto updates the AFL. However, we I'm sure there are areas that we need to look at. CDPH is putting out guidance soon for this.

Q: Is the recommendation for vaccine going to be use up all initial allotment and not reserve second half of dose a not reserve half the dose for the second dosing?
A: Per Heidi: there will be an AFL to outline the criteria. We are working in tandem with the vaccine taskforce and we will be giving more guidance about vaccine task force and have more representation of them on this call.

Q: Regarding AFL 20-88, with the clarity that the recommendation of testing all personnel is a recommendation and not a requirement, this All Facilities Letter (AFL) requirements represent a huge diversion of critically needed resources our planning team time, materials, personnel protesting and high cost when we are in the midst of the largest surge to date. At the same time we are engaged in critical planning for vaccine administration and delivery, I'm curious to the evidence basis that requiring the level of testing for all Healthcare providers that that will be more beneficial than increased diligence and enforcement of appropriate masking and social distancing throughout the hospital will outweigh the huge negative impact that implementing this portion of the AFL will cause for hospitals and healthcare system. Also, I would like to mention that the publication of this AFL has created a real challenge for hospitals with organized labor, because with this in their hands it will be used against hospitals that don't proceed with testing all Healthcare personnel.
A: Heidi: I appreciate your feedback and comments. Keep in mind that we all have the same goal in mind, we all understand that there is competing priorities with planning and strategies when it comes

to planning. Part of that planning that is equally important is how do we keep our healthcare frontline workers safe. That is something important to have in place, whether that's the facility going to the recommendation of weekly testing for all healthcare personnel who are directly involved, or whether they do as we indicated in AFL to evaluate high risk staff first, but to make sure that there are policies and procedures in place to test your own staff.
A: Dr. Epson: I will add that the testing recommendation is based on modeling work that predicts decreases infectious work days for healthcare personnel to be expected on the basis of different frequencies of screening of asymptomatic healthcare personnel and predicted substantial decrease with weekly testing more so then less frequent intervals of testing, hence the weekly screening interval. We all agree and appreciate that testing alone without other control measures in place is also unlikely to substantially reduce transmission and outbreaks. The measures that you described, strict adherence to mask use and social distancing are critical and will continue to be critical even with a testing plan in place.

Q: If we have more than 500,000 and 1 million active facing patient personnel in California that would be somewhere around a 1 in 1,000 probability per person per day.
A: Heidi S: We haven't been testing all healthcare workers. I would presume that if we test all healthcare workers today, we would have quite a higher percentage of positivity rate today.

Q: Wondering if there was any further update on COIVD-19 vaccine and expected delivery dates?
A: Heidi S: We will have someone from the Vaccine taskforce join us to provide a vaccine task force update. We do not have specific dates on when those vaccine will be delivered to each facility. Generally, we should be expecting our shipment of vaccine over the next week. Form there operationally be able to implement these, depending on the type of vaccine that dictates where we can send it and to what area due to storage requirements.

Q: Regarding AFL 20-88, what is the recommendation on Healthcare personnel that received the vaccine, will they be required to receive weekly asymptomatic prophylactic testing?
A: Dr. Epson: That is something we are actively discussing along with immunization colleagues; how are we going to adapt and change to screening testing and response testing. I do not have a comprehensive answer just yet, but we are evaluation and reevaluating the need for weekly testing after the vaccine is implemented. We think it likely that after the administration of vaccine and completion of both doses that we will be able to scale down the universal healthcare screening or potentially limit screening to unvaccinated healthcare personnel. Contingent to vaccination level at the hospital.

Q: On new quarantine guidance, my understanding from the CDC guidance is if the local health jurisdiction authorizes it there is potential for a 7-10-day release, even though they are still recommending 14 days. For the seven day release they are requiring testing at day five or later, but no release until 7 seven days. The CDPH guidance states that it must be testing after day five not on day five. Can you clarify can the testing be on day five with release of day seven, or does the testing have to wait until day six.
A: Dr. Harriman: this could be an error I'll have to check on that.

Q: For the positivity rate do we go to the CDPH blueprint for safer economy? Also, If we are over 10% for positivity rate what would be our timing, or when will be doing the testing?
A: Dr. Epson: Yes, the CMS requirement is that facilities located in counties with greater than 10% test positivity implement twice a week screening testing for healthcare personnel. You are correct, we are recommending using the CDPH blueprint for a safer economy to identify test positivity for your county. I think the exact spacing of the testing I think isn't specified, but every 3-4 days seems reasonable. Your facility can consider the logistics of staff schedule and when the testing site/staff are available to accomplish this. The testing frequency does presume a 48-72 hours testing turnaround time

Q: When is the website updated, the blueprint for a safer economy?
A: Dr. Peters: The blueprint is updated Tuesday around noon.

Q: Can you clarify the new quarantine guideline in the setting of Long-Term Care (LTC) setting and other congregate setting, can we use the exclusion from work for exposed healthcare workers following definitive exposure? Can we use the 7-10-day guidelines for those healthcare personnel who are at work with highest risk population or should we continue to use the 14-day recommendation?
A: Per Dr. Epson: I believe that the 14 day is provided as an option in addition to these new 7-10 options. I would suggest checking with local health department on what they will be recommending specifically for residents or healthcare personnel in highest risk congregate setting.
A: Dr. Jacobson: It's up to local health departments, they can be more conservative than CDPH guidance. I know that there was some interest in having consistency guidance, but that is certainly up to the local health departments to manage the guidance as they think best. Nothing changed really about the 14 days, using the 7-10 days leaves some risk involved in that decision.
A: Heidi S: We have found that most outbreaks in SNF have come from healthcare workers. Through contact tracing we have found that some of our worst outbreaks have come from healthcare workers engaging in activities during the holidays, birthday parties, etc. We are going to be starting a campaign and make material available that facilities can download. These are campaigns saying thank you for being heroes at work, but to remind healthcare workers to be models outside of work. We are trying to reiterate messaging on how important it is for frontline workers to practice social

Q: In one has tested positive with PCR testing with no signs and symptoms and three days later is tested to make sure it's not a false-positive with SARS antigen FIA test and the results come back negative, what should we do in this case? Still isolate? And for how long?
A: Dr. Watford: it is not recommended to retest on someone who was positive with a molecular assay, because the retest by the antigen assay was done more than 48 hours it is not considered to be a confirmatory test. You would not confirm a molecular test with an antigen test. This scenario is difficult to interpret, you would have to align it with the clinical manifestation, I would recommend is that you do another nucleic acid amplification assay rather than rely on antigen test.
A: Dr. Epson: Essentially for healthcare workers in higher risk setting it would be managed as a true positive. The reason for a confirmatory test needing to be done within 48 hours is that if another test is done greater than that amount of time a different result might reflect changing viral dynamics in an individual person and so you could have someone who was truly positive and then a few days later test negative. Generally, I would manage these positives by PCR or other nucleic acid test as true positives unless there is a compelling reason to suspect a false positive. Given how much transmission there is in the community there is a high pre-test probability in an asymptomatic individual, even in an

asymptomatic individual of the positive test representing a true positive. Again, I would manage these as a true positive, no need to do a second test especially after the 48 hours, and I would manage their contacts as having potential expose too, depending on timing and nature of contact.

Q: If Staff were exposed to this individual, they have no signs and symptoms, and their test result is negative can they continue working?
A: Dr. Epson: That depends on a couple of things. We have our new quarantine guidance that offers shortened quarantine with a test, but that test would need to be collected at the appropriate interval since the last exposure. Also, your local health department may have more stringent requirements based on the setting. Finally, there is guidance that's in the FAQ for hospital testing, but is applicable to skilled nursing facilities regarding strategies on mitigating staffing shortages which allow under certain circumstances for individuals with a known exposure to continue to work such as: ongoing staffing shortage, etc. I will say in a skilled nursing facility when you have identified any case in your facility, either in a resident or healthcare personnel, we are considering there to be a potential exposure quite broadly within a facility and that's why we do a widespread response testing to reduce risk to potential exposure.

Q: We are in the process of finalizing our mitigation plan in response to ALF 20-88 and one of our platforms just released a product it's a high throughput antigen testing, but it only received an Emergency Use Notification (EUN) and pending Emergency Use Authorization (EUA). We wanted to know if this method would be acceptable to serial testing or screening.
A: Dr. Watford: Yes, it will also be in the notes and you can google updated CDC antigen testing guidance and find it that way.

Q: Regarding AFL 20-88, there's real concern about the burden it is. You mentioned modeling earlier, can you provide the models you mentioned?
A: Per Dr. Jacobson: These models come from Harvard and Stanford and I am happy to share the references to these articles via the email process.

Q: How will the requirements from AFL 20-88 be surveyed?
A: Heidi S: I will defer some of those questions to the testing taskforce and Dr. Epson, as they are recommendations, we can't survey to it, but we can review the required testing plan to make sure that the hospital thought of everything on the AFL list.

Q: California has taken a larger belt and suspenders approach compared to other states, but what have you heard about what folks are doing in other areas.
A: Heidi S: I will defer some of those questions to the testing taskforce and Dr. Epson. California was front and center in many courses of action in pandemic. I think that yes California may be forward leaning, but I don't think that's a bad thing when you look at mortality rates per 1,000 people and case rates per 1,000 people. I think the end goal is about how can we use science and safe practices to identify and contain as soon as possible.

Wednesday Webinar: 3–4 p.m., Attendee Information:
Register at: https://www.hsag.com/cdph-ip-webinars
Call-In Number: 415.655.0003 **Access Code:** 133 788 3426