

Everybody Has A Plan

"Guidance for Dental Health Care Providers Responding to Cases of Covid-19"

Dr. Deanna Aronoff, ACPHD, Clinical Dental Director

"Preprocedural COVID-19 Testing"

Dr. Louis Girling, ACPHD, California Children's Services Medical Director

"Considerations for Establishing COVID-19 Testing Within Your Dental Practice"

Dr. Kristina Hsieh, ACPHD, Director Public Health Laboratory Services

September 24, 2020

5:30 PM to 6:30 PM



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Tonight's Moderators:

Bhavana Ravi DDS

Community of Practice Manager
Healthy Teeth Healthy Communities
Office of Dental Health
Alameda County Public Health Department

Deanna Aronoff DDS,MSD

Clinical Dental Director
Office of Dental Health
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Huong Le DDS

Chief Dental Officer
Asian Health Services



Housekeeping Tips

- Please put your cell phones and computers on mute
- Please ask your questions in the chat box
- If the meeting drops, please go to original link in your email and rejoin the meeting
- This session is being recorded
- If you have further questions regarding any of the presentations, please email: deanna.aronoff@acgov.org



Resources

- The recording for tonight's webinar will be available on the Alameda County Public Health Department website

<http://www.acphd.org/2019-ncov/providers/dental-services.aspx>

- Link to register for Alameda County Health Alerts

<https://tinyurl.com/yacfk49q>



Special Thanks to:

Dr. Huong Le
Chief Dental Officer
Asian Health Services

Alameda County Dental Society

Southern Alameda County Dental Society

Berkeley Dental Society

Guidance for Dental Health Care Providers Responding to Cases of COVID-19

Deanna Aronoff DDS, MSD

Clinical Dental Director, Office of Dental Health

September 24, 2020



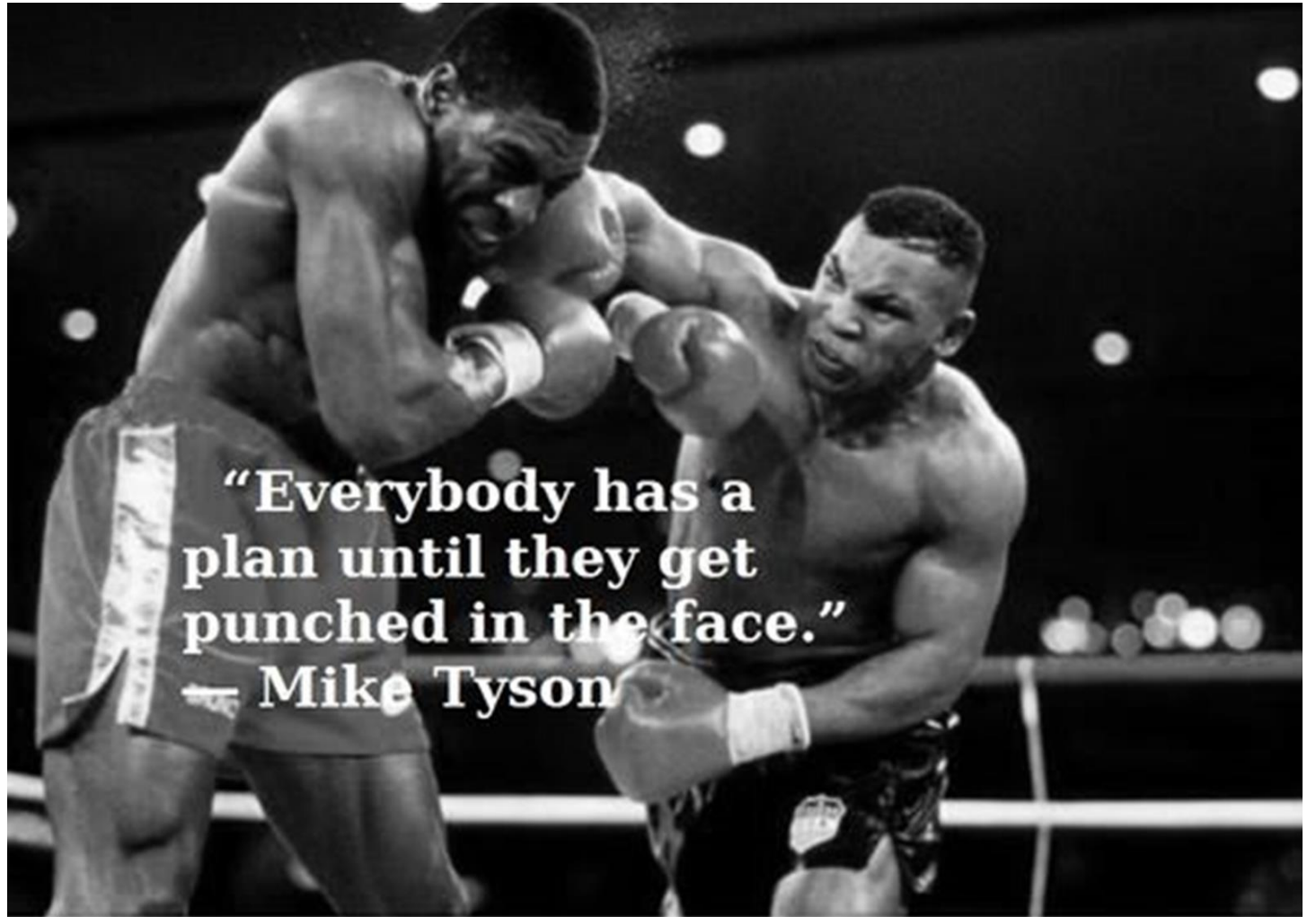
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How does SARS CoV-1 compare to SARS CoV-2?

- In 8 months, SARS-CoV-1 infected 8,100 people in limited areas of 26 countries.
- Within 5 months, SARS-CoV-2 has infected 2.6 million people. Of these, about 40-45% are asymptomatic carriers.
- SARS-CoV-2 is a very contagious virus partly because one is infectious 2 days before having symptoms or being asymptomatic while being out in public. This is another example of why people need to wear masks.



Overview and Objectives

By the end of this portion of the webinar, participants will be able to identify:

- What to do if an employee is symptomatic for COVID-19
- What to do if an employee is diagnosed with COVID-19
- What to do if patient is positive for COVID-19 and had visited the office in the 48 hours before (a) testing positive or (b) becoming symptomatic and later diagnosed with COVID-19
- What other precautions should a dental office take when a patient or employee with COVID-19 is identified

If an Employee is Symptomatic for COVID-19



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Document and Send Employee Home

Document the date employee reports symptoms and **send employee home** if they are at work.

Symptoms include but are not limited to:

- Fever ($\geq 100^{\circ}$ F) or Chills
- Fatigue
- Sore Throat
- Cough
- Muscle or Body Aches
- Congestion/Runny Nose
- Shortness of Breath
- Headache
- Nausea or Vomiting
- Difficulty Breathing
- New Loss of Taste or Smell
- Diarrhea



Provide Return-to-Work Criteria

- Employee may return to work when they meet the criteria laid out in the CDC Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection.
- Criteria to return to work and release from isolation include:
 - a) At least 10 days have passed since symptoms first appeared; and
 - b) At least 24 hours have passed since last fever without the use of fever-reducing medications; and
 - c) Symptoms (e.g., cough, shortness of breath) have improved.



Suggest Medical Evaluation to Employee

- Ask employee to contact their primary care provider about medical evaluation for possible COVID-19, which may include testing.
- If the employee is tested and willing to share, request they communicate the date of the test, the test result, the source of specimen (e.g., blood, nose, throat, etc.), and what type of test was used (e.g., PCR, antigen, etc.) if known. Document this result in your records.

If an Employee is Diagnosed with COVID-19



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Inform Dental Health Care Personnel (DHCP)

Notify dental health care personnel (DHCP) that someone in the office was diagnosed with COVID-19, but do not disclose who this person is unless the employee with COVID-19 has agreed to be identified.

Revised Definition of Close Contact for Alameda County:

Close contacts are people who stayed within 6 feet of a COVID-19 infected person for more than 15 minutes after that person was diagnosed or up to two days before they first developed symptoms. This applies even if both people are wearing a face covering, mask, or an N95 respirator. Close contact can also take place during brief interactions where there is unprotected direct contact with the COVID-19 infected person's body secretions (sneezing, coughing, sharing utensils, saliva). Cumulative exposures that add up to 15 minutes within a day may be considered close contact depending on intensity of exposure (e.g. did the person have multiple interactions in a confined space with a symptomatic COVID-19 infected person). (So if a receptionist wearing a facemask was sneezed on by a COVID-19 positive patient.)

Close contacts do not include healthcare workers who use infection control precautions, including all recommended personal protective equipment, while caring for someone with COVID-19.



Assess the Close Contacts (1/2)

Assess the contacts during the 48 hours before the COVID-19 positive employee had symptoms or when they had the test taken if they have no symptoms.

Close contact is defined as being within six feet or closer for 15 minutes

This includes staff as well as patients



Assess the Close Contacts (2/2)

- Ask employee with COVID-19 to identify close contacts among staff and patients during that 48- hour time frame
- If employee is willing to be identified, ask the other employees to identify their close contacts during the 48-hour time period.
- Identify what Personal Protective Equipment (PPE) if any, was being worn by the employee or other staff at that time.
- A non-fit tested N95 respirator is considered as NO protection and a close contact.

Ask Close Contact to Self-Monitor Symptoms

- Ask any DHCP who are close contacts to self-monitor for fever or symptoms consistent with COVID-19 for at least 14 days after exposure.
- They have the option to, though are not required, to obtain COVID-19 testing. Best time to test is 4-10 days after contact to have enough viral load in the nasal pharynx to be detected by COVID-19 test.
- Even if the DHCP has a negative COVID-19 test, they still have to quarantine for 14 days if they had a high risk or close contact. (Even if they are tested again on Day 10 and it's a negative test)



Send Home Potentially Exposed DHCP

Send home any DHCP who had close contact and at least one of the following criteria are met:

- DHCP was not wearing a fit-tested respirator or a facemask
- DHCP was not wearing proper eye protection and the employee with COVID-19 was not wearing a cloth face covering or facemask



Contact Potentially Exposed Patients

- If the DHCP weren't N95 respirator fit tested, then the incident is considered a close contact and patients will have to be notified
- Call the patient, identify yourself and your office
- Calmly state that there was a person in the office that tested positive for COVID-19 while you were here
- "We are concerned for your health and we want to be upfront about this possible exposure"

Contact Alameda County Public Health Dept.

In accordance with California State COVID-19 reporting requirements, please use the [Workplace Case and Contact Reporting Form](#) to report a confirmed or suspected COVID-19 case in the workplace, and any associated closed contacts.

For questions related to positive employees in the workplace, please contact the COVID Workplace Response Team at COVIDworkplace@acgov.org.



Contact California Workers Compensation

Governor Newsom's Executive Order N-62-20 provides that all California employees who work at a jobsite outside their home at the direction of their employer who test positive for COVID-19 within 14 days of working at their jobsite are presumed to have contracted any COVID-19 related illness at work for the purposes of awarding workers compensation benefits.



Contacting Cal/OSHA

- From California Department of Public Health COVID-19 Employer Playbook July 28, 2020
- California employers must record a work-related COVID-19 fatality or **illness** if it results in one of the following:
 - a) Death;
 - b) Days away from work;**
 - c) Restricted work or transfer to another job,
 - d) Medical treatment beyond first aid,
 - e) Loss of consciousness or a significant injury or illness diagnosed by a physician or other licensed health care professional



Recording Cases of COVID-19 Cal/OSHA

- Employers must record case on their 300, 300A and 301 or equivalent forms
- California Code of Regulations, title 8, Chapter 7, Subchapter 1, Article 2 for Employer Records of Occupational Injury or Illness

Reporting COVID-19 Cases to Cal/OSHA



- If your employee becomes ill while at work and is admitted as in-patient at a hospital (doesn't matter how long employee is in hospital)
- You must report to Cal/OSHA within **eight hours** of the time you were notified of the hospitalization
- You should report to the nearest Cal/OSHA office.
- For more information, visit Cal/OSHA, Recording and Reporting Requirements for COVID-19 Cases Frequently Asked Questions

Cal/OSHA Interim Guidance on COVID-19 for Health Care Facilities: Severe Respirator Supply Shortages Note: 8/6/20

4.0 Use Fit Testing Methods that Maximize Respirator Supplies and Fit Testing Efficiency. Initial **respirator fit testing** is required:

- a) Before an employee uses a respirator
- b) When an employee changes to a different model, make, or size of respirator

Note: There are no changes to these requirements, but the annual fit testing requirement has been waived.

So if I don't provide N95 Respirators to my staff, what could possibly go wrong?

Cal/OSHA closes dental clinic at San Quentin Prison citing practices that have contributed to the spread of SARS CoV-2 such as failure to provide air-purifying respirators to the dental staff.



U.S. Department of Labor Cites Massachusetts Dental Practice for Not Fully Implementing Workplace Respiratory Protections



- U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) cited the Georgetown Dental LLC for violating respiratory protection and other standards at the Georgetown, MA, location.
- OSHA cited the dental practice for failing to provide medical evaluations and fit testing for employees required to wear N-95 respirators as protection against coronavirus and other citations.
- OSHA cited the dental practice for six serious violations with penalties of \$9,500.00 on September 16, 2020.



And the lawyers are looking
for that pot of gold at
the end of the rainbow

“Lawyers predict a huge
explosion in worker class
actions over COVID-19”

LAW.COM April 16, 2020

“The high demand for
lawyers amid the
coronavirus pandemic”

ABA Journal March 17, 2020

If A Patient Tests Positive for COVID-19 Within 48 Hours of Their Last Visit



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Documentation

- Document the date the patient notified the dental office.
- Ask the patient when they first noticed symptoms of COVID-19
- Ask when they were tested, what specimen and type of test used
- Assess their close contacts during the appointment:
 - Close contact is defined as being within six feet or closer for 15 minutes within 48 hours of COVID-19 positive patient having symptoms or getting a positive test result
 - Also if aerosol generating procedure is performed and there is any exposure, then it's a close contact.
 - Identify what Personal Protective Equipment (PPE) was worn by the staff during the patient encounter, was it fit tested and appropriate?



Next

- Ask any DHCP who was a close contact to self-monitor for fever or symptoms consistent with COVID-19.
- They should have the option to be tested. For best results, have testing done at least four days after possible exposure.
- There are free testing sites within Alameda County as shown on Alameda County Public Health Department webpage or they can contact their primary care provider for testing.



Homeward Bound

Send home any DHCP to quarantine for 14 days if they had close contact with a COVID-19 positive patient, and at least one of the following criteria are met:

- DHCP was not wearing a respirator or facemask (if not N95 fit tested then it's considered as if not wearing one) OR
- DHCP was not wearing proper eye protection (goggles or full-length face shield) OR
- Aerosol generating procedure was performed on COVID-19 positive patient and the appropriate PPE was not worn by DHCP. **This includes wearing a non-fit tested N95 respirator.**

Respirators

Respirators with exhalation valves are NOT recommended for source control. If this type of respirator is the only option for source control, the exhalation valve should be covered with a facemask that does not impact the fit of the respirator.



Precautions upon Identifying a Positive Case



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Perform Environmental Cleaning

- At a minimum, perform an environmental cleaning and disinfection of all high touch surfaces and clinical instruments.
- Refer to the CDC's Infection Prevention and Control Guidance for Dental Settings during the COVID-19 Response for more guidance.



Ask All Staff to Self-Monitor for Symptoms

After an employee or patient is diagnosed with COVID-19, all staff should continue to monitor for symptoms and make sure to not come to work if feeling sick.

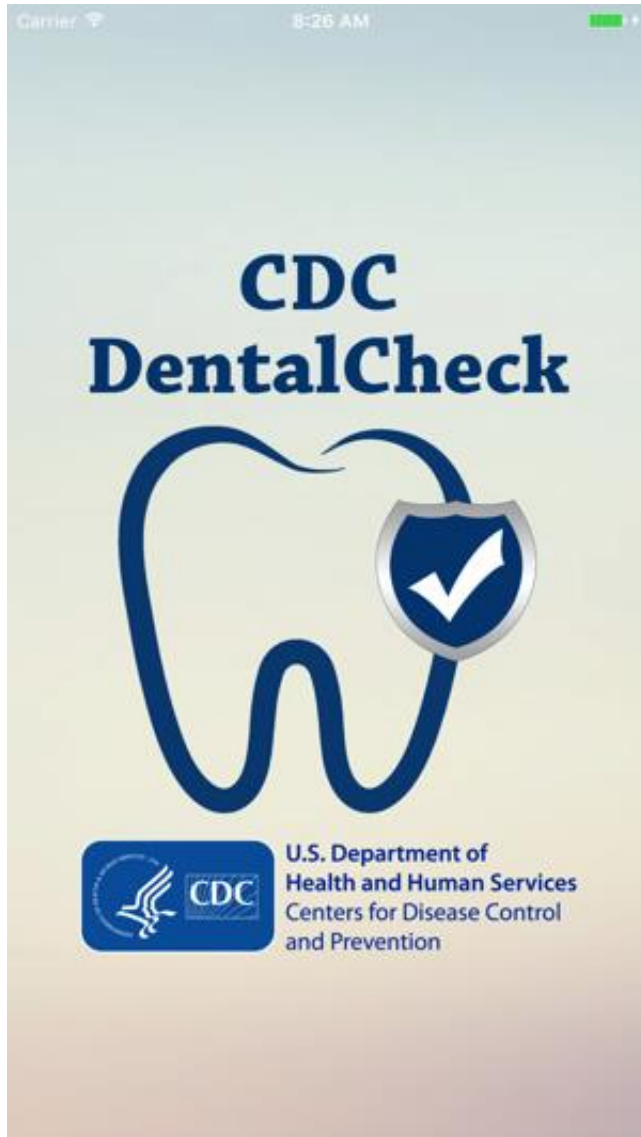
Where Do Many Dental Office Outbreaks Occur?

- Employees shouldn't congregate in the break room
- Stagger breaks
- Don't share food or utensils
- Employees may want to eat outdoors with six feet social distancing or in their cars by themselves



Encourage Testing for High Priority Contacts

- If someone is identified as a close contact (within 6 feet for 15 minutes or present during an aerosol-generating procedure without appropriate PPE) the close contact is a high priority for testing and should obtain testing if desired.
- This means that their health care provider should make every effort to have this close contact tested.
- A COVID-19 test is most likely to be positive between 4-10 days after the exposure.

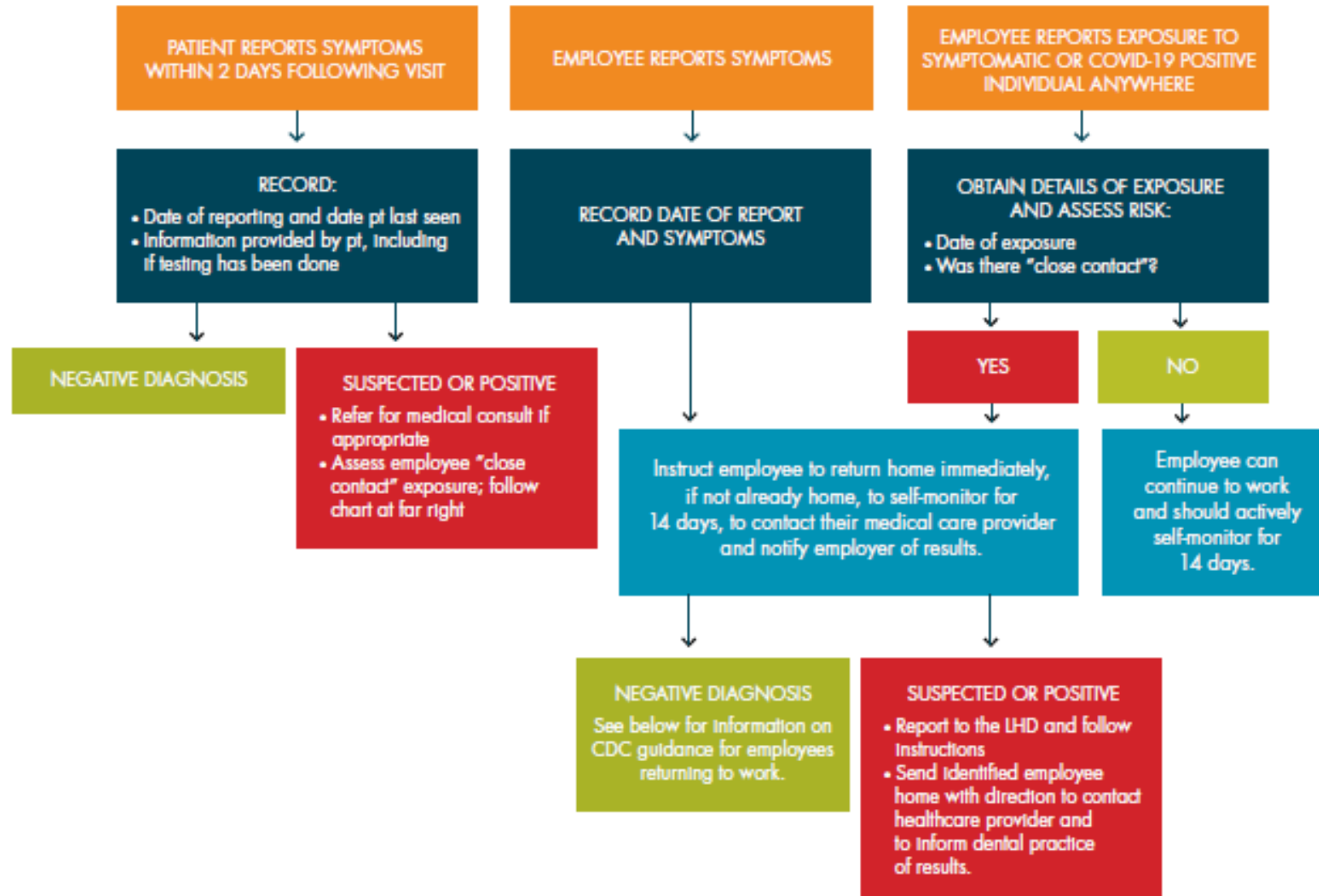


CDC Dental Check App

- Create your own checklist
- Access Infection Prevention Practices
- Access CDC COVID-19 Most Recent Guidance Updated
- Links to OSHA, EPA, FDA

Reporting Symptoms/Positive Test for COVID-19

Regulatory Requirements



Life imitates science fiction
and hope is on the horizon



“Scotty, I need
warp speed in 3
minutes or
we’re all dead!”

Operation Warp Speed Vaccine Candidates

Candidate	Technology	Single dose	Stage
Moderna (mRNA-1273)	Messenger RNA	No	Phase 2a clinical trial
BioNTech/Fosun Pharma/Pfizer (BNT162a1, BNT162b1, BNT162b2, BNT162c2)	Messenger RNA	Potentially	Phase 1-2 clinical trials
Merck, Sharpe & Dohme and the International AIDS Vaccine Initiative	Recombinant vesicular stomatitis virus vector	Unknown	Preclinical
Johnson & Johnson/Janssen Pharmaceuticals	Replication-defective human adenovirus 26 vector	Yes	Phase 1-2a clinical trials
AstraZeneca and the University of Oxford (ChAdOx1 nCoV-19)	Replication defective simian adenovirus vector	Yes	Phase 1-2 clinical trials



Resources

[Guidance for Dental Health Care Providers Responding to Cases of COVID-19](#) (ACPHD)

[Reporting Symptoms/Positive Test for COVID-19 Regulatory Requirements](#) (CDA)

[Best Practices for Infection Control in Dental Clinics During the COVID-19 Pandemic](#) (OSAP)

[Guidance for Dental Settings](#) (CDC)

[Dentistry Workers and Employers](#) (OSHA)

Thank You

Deanna Aronoff DDS, MSD

Clinical Dental Director, Office of Dental Health

Deanna.Aronoff@acgov.org

A solid red triangle is located in the bottom-left corner of the slide, pointing towards the center.

Preprocedural COVID-19 Testing

Louis Girling, Jr., MD, FAAP

COVID-19 Response Clinical Guidance Lead Physician

Thursday, September 24, 2020



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Overview and Objectives

By the end of this section, participants will be able to:

- Differentiate between the types of available COVID-19 tests
- Screen patients appropriately for COVID-19 before dental office visits
- Determine appropriate actions based upon results of COVID-19 screening
- Use SARS-CoV-2 testing to guide timing of non-urgent dental procedures, especially if an aerosol-generating procedure is anticipated



COVID-19 Testing Technology



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Two Categories of COVID Tests

- **Diagnostic** (detects active infection)
 - Molecular (NAAT) Tests
 - Antigen Tests
- **Serologic** (detects past infection)
 - Antibody Tests



Nucleic Acid Amplification Tests (NAAT)

- "Molecular" diagnostic tests which detect viral genetic material
- Preferred and most common laboratory test for diagnosing active COVID-19 infections in both symptomatic and asymptomatic patients
- May be sensitive enough to detect shedding of viral nucleic acids in patients who have recovered from active infection and are no longer infectious
- Acceptable specimens may include nasopharyngeal (NP), nasal or oropharyngeal swab; sometimes saliva



Nucleic Acid Amplification Tests (NAAT)

- NAATs include
 - RT-PCR
 - moderate to high complexity laboratory
 - point-of-care - Cepheid GeneXpert Xpress SARS-CoV-2
 - Isothermal NAAT (Abbott ID NOW)
 - Transcription-Mediated Amplification or TMA (Hologic Panther System)



Antigen Test

- Diagnostic: detects viral nucleocapsid protein
- Primary advantages include low cost, high portability, and rapid turnaround time – some yielding results in 15 minutes
- Best utilized when pre-test probability is high
- Negative results should be considered presumptive and require confirmation using a non-point-of-care NAAT
- Administered via nasal or throat swab



Antibody (Serology) Test

- Detects antibodies to the virus
- Identifies past SARS-CoV-2 infection (not used to diagnose current infection)
- Administered via finger stick or blood draw
- Researchers do not know whether the presence of antibodies provides immunity to SARS-CoV-2, post infection



Preprocedural Testing





Dental Services During COVID-19 Pandemic

- Urgent medical and dental procedures have continued in both outpatient and inpatient settings
- May 13, 2020: Alameda County Public Health Department (ACPHD) released a [Health Advisory](#) encouraging medical and dental providers gradually to resume non-urgent clinical services, with several important caveats
 - Use appropriate PPE
 - Avoid aerosol-generating procedures
 - Use airborne infection isolation room (AIIR) when patient with COVID-19 requires emergency dental services





Joint Statement on Perioperative Testing

- April 29, 2020: “Joint Statement on Perioperative Testing for the COVID-19 Virus” release by Anesthesia Patient Safety Foundation (APSF) and American Society of Anesthesiologists (ASA)
- Facilities should implement patient screening and testing policies that provide useful preoperative/preprocedural information about patient’s COVID-19 status
- Test results should be factored into determinations about the appropriate timing of elective and non-urgent procedures, in order to:
 - 1) Reduce the exposure risk to staff and other patients
 - 2) Enhance patient safety, since there may be additional clinical risks when invasive procedures are performed in a patient who is actively infected with SARS-CoV-2 or recovering from COVID-19 illness.

Alameda County COVID-19 Data Snapshot



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Alameda County
Total Cases

20641

Alameda County
Total Deaths

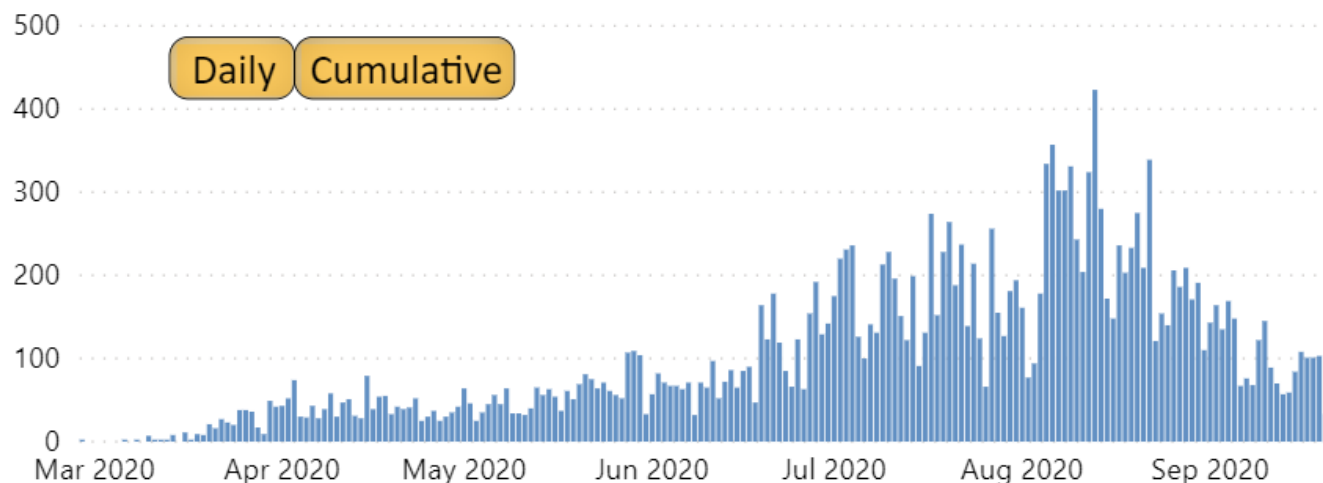
374



Alameda County COVID-19 Dashboard

Alameda County Total Daily Cases

Data from last five days especially subject to change.



Cases

Case Rates

Deaths

Death Rates

Berkeley LHJ
Cases

671

Berkeley LHJ
Deaths

8

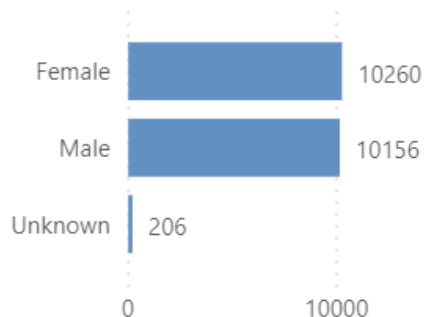
Alameda County
LHJ Cases

19970

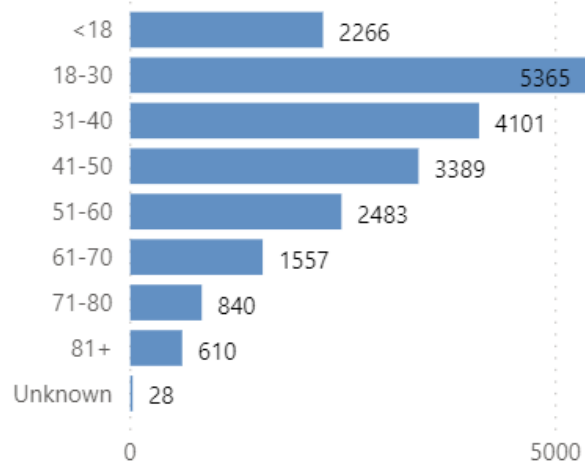
Alameda County
LHJ Deaths

366

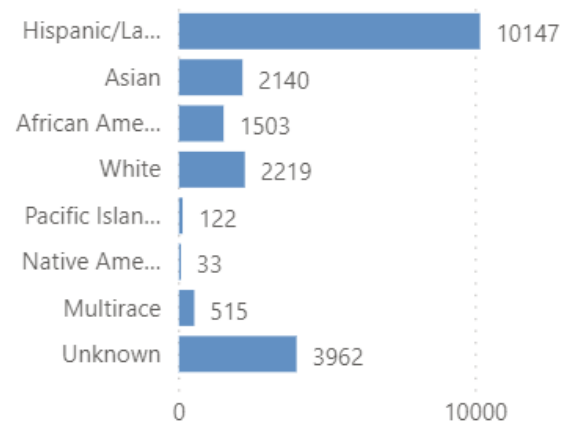
Alameda County Total Cases by Gender



Alameda County Total Cases by Age Group



Alameda County Total Cases by Race/Ethnicity



Jurisdiction	Cases
Alameda County	20,641
Berkeley LHJ	671
Alameda County LHJ	19,970

Various Populations	Cases
Under Investigation	265
Homeless	185
Address Unknown	241

Cities	Cases
Alameda	399
Albany	55
Dublin	272
Emeryville	85
Fremont	1,392
Hayward	2,978
Livermore	862
Newark	555
Oakland	8,165
Piedmont	33
Pleasanton	433
San Leandro	1,116
Union City	742

Unincorporated Areas	Cases
Eden Area MAC (Ashland, Cherryland, Hayward Acres, San Lorenzo)	1,292
Castro Valley MAC	522
Fairview MAC	152
Sunol	12
Remainder of County	35

Alameda County Total

Tests

513049

Tests per 1000 persons

311.1

Positives

24448

Percentage Positive

4.8%

Berkeley LHJ

Tests

45378

Tests per 1000 persons

380.8

Positives

749

Percentage Positive

1.7%

Alameda County LHJ

Tests

467671

Tests per 1000 persons

305.7

Positives

23699

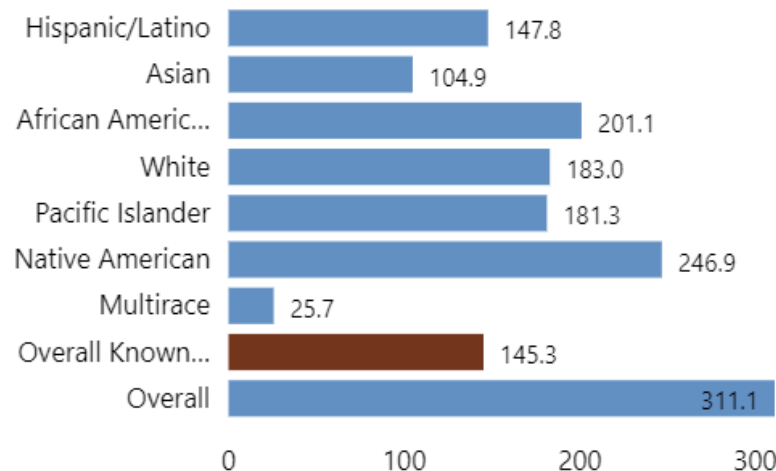
Percentage Positive

5.1%



Alameda County COVID-19 Testing Dashboard

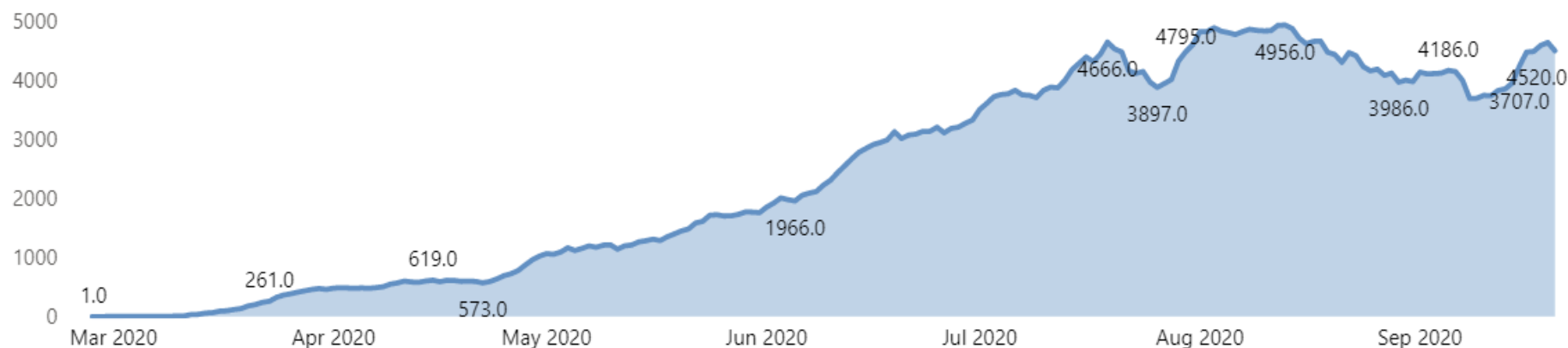
Alameda County Total Testing Rate per 1,000



Alameda County Total Rolling 7-Day % Positive Tests



Alameda County Total Tests, Rolling 7-Day Average





State Data Monitoring Metrics

	Higher Risk → Lower Risk of Community Disease Transmission***			
	Widespread Tier 1	Substantial Tier 2	Moderate Tier 3	Minimal Tier 4
Measure				
Adjusted Case Rate for Tier Assignment** (Rate per 100,000 population* excluding prison cases^, 7 day average with 7 day lag)	>7	4-7	1-3.9	<1
Testing Positivity^ (Excluding prison cases^, 7 day average with 7 day lag)	>8%	5-8%	2-4.9%	<2%



Dental Setting Risk Factors

Factors that increase risk of transmission in dental settings are:

- Duration of exposure
- Physical proximity
- Aerosol generating procedures
- Presymptomatic infection - viral load often very high in 2 days prior to symptom onset
- Prevalence of asymptomatic infection



Asymptomatic/Presymptomatic Transmission

Many people who test positive have **NO SYMPTOMS**.



Definition of Close Contact

- **What makes someone a “close contact” of a person with COVID-19?**
- Close contacts are people who stayed within 6 feet of a COVID-19 infected person for more than 15 minutes after that person was diagnosed or up to two days before they first developed symptoms. This applies even if both people are wearing a face covering, mask, or a N95 respirator. Close contact can also take place during brief interactions where there is unprotected direct contact with the COVID-19 infected person’s body secretions (sneezing, coughing, sharing utensils, saliva). Cumulative exposures that add up to 15 minutes within a day may be considered close contact depending on intensity of exposure (e.g., did the person have multiple interactions in a confined space with a symptomatic COVID-19 infected person).
- Close contacts do not include healthcare workers who use infection control precautions, including all recommended personal protective equipment, while caring for someone with COVID-19.

Actions Requested of Clinicians





Implement COVID-19 Mitigation Policies

"While there is active transmission of SARS-CoV-2 in Alameda County, ACPHD recommends that ... dental providers implement policies and strategies that include

- screening of all patients for symptoms of COVID-19 and
- selective preprocedural testing of patients undergoing non-emergent ... dental ... procedures that may involve intubation or the generation of biological aerosols."

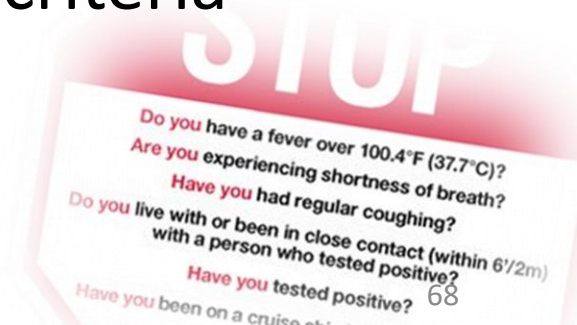


Screen All Patients Prior to Appointment

All patients should be screened for symptoms of COVID-19 and for close contact with a COVID-19 case prior to appointment.

- Patients who report symptoms should be referred for additional medical evaluation.
- Patients who report close contact with a COVID-19 case within the prior 14 days should quarantine and should not undergo elective procedures until they have met quarantine release criteria

See [Alameda County COVID-19 Laboratory Testing Guidance for Clinicians](#) for more information.





Consider Testing Before Planned AGPs

"Facilities and providers may consider testing all other patients for SARS-CoV-2, using a NAAT test prior to undergoing non-emergent ... dental ... procedures that may involve intubation or the generation of biological aerosols."

See [Alameda County COVID-19 Laboratory Testing Guidance for Clinicians](#) for more information.





Confirm Negative Test Result

- Before proceeding with any aerosol-generating procedures, the dentist should confirm the negative test result via
 - review of hard copy, email, or faxed result, or
 - by consulting the patient's electronic medical record).





Exercise precautions – even with a Negative Test Result

- Remember that a negative test does not definitively rule out SARS-CoV-2 infection.
 - False negative test results may occur, depending on the testing platform used
 - Negative results may be obtained from positive patients during incubation period
 - Patients could become infected after the test is performed



Actions Based on Positive Test Results



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Positive Test Result

If a patient tests positive for SARS-CoV-2 (indicating active infection) elective procedures should be delayed until the patient:

- 1) Is no longer infectious;
- 2) Has demonstrated recovery from COVID-19; and
- 3) Meets CDC's criteria for release from isolation, as described in the [ACPHD Health Advisory](#) on July 29, 2020





Which test should I use?

- Ideal test for dental setting would be a
 - diagnostic test with
 - high negative predictive value and
 - rapid turnaround time (same day best; 24-48 hour acceptable)
 - Examples:
 - RT-PCR performed by lab with 24-48 hour turnaround
 - Cepheid GeneXpert Express SARS-CoV-2
 - (maybe) Abbott ID NOW
 - (in future?) rapid antigen testing
- Become familiar with the performance of testing platforms available to your practice setting
- Rely only on results of a test with strong negative predictive value.

Resources

[Alameda County COVID-19 Laboratory Testing Guidance for Clinicians](#)

[Interim Guidance on Testing for SARS-CoV-2 before Non-Urgent Surgical, Dental, and Diagnostic Procedures](#)

[Resumption of Non-Urgent Health Care Services in Alameda County](#)

Thank You

Louis Girling, Jr., MD, FAAP

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Considerations for Establishing COVID-19 Testing within Your Practice

Kristina Hsieh DrPH, HCLD (ABB)

Director of Public Health Laboratory Services

September 24, 2020



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Overview and Objectives

By the end of this section webinar, participants will be able to:

- Identify COVID-19 point-of-care testing options
- Understand COVID-19 regulatory and reporting requirements
- Access COVID-19 laboratory testing resources

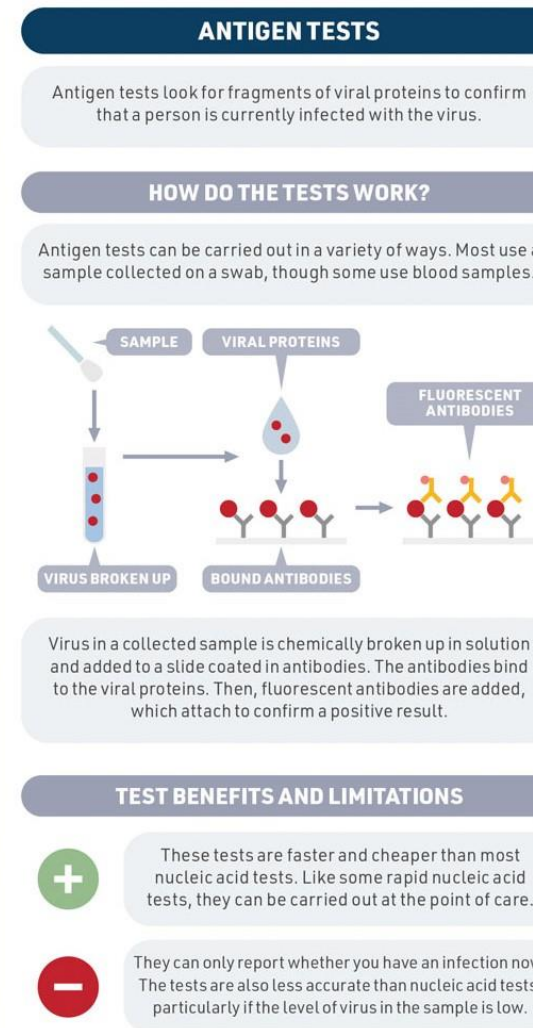
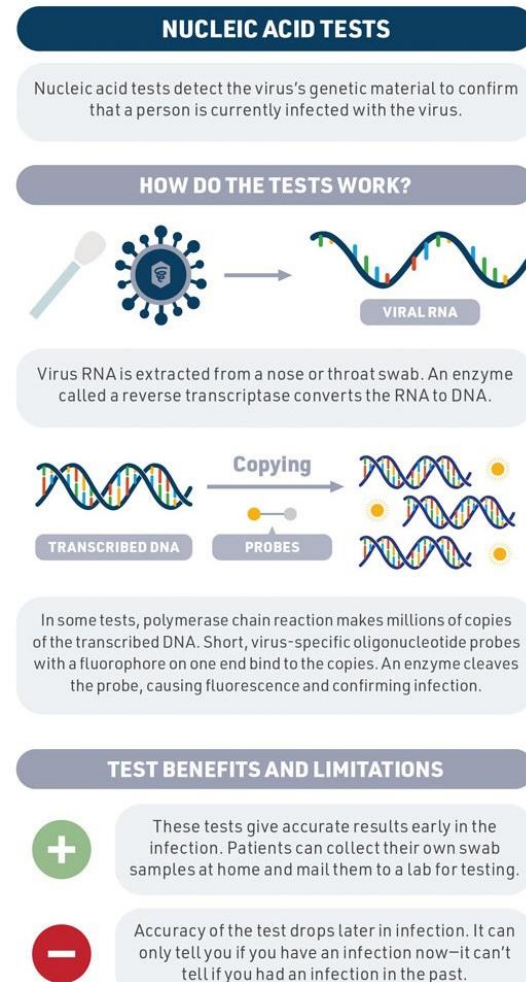
Centers for Medicare & Medicaid Services (CMS)-CLIA

- Congress passed the Clinical Laboratory Improvement Amendment (CLIA '88): Establish quality standards for laboratory testing
- CLIA regulations are based on the complexity of the test method
 - **Waived**
 - Provider Performed Microscopy Procedures
 - Moderate Complexity
 - High Complexity

Point of Care Testing Options

FDA EUA Approved POC Tests CLIA Certificate of Waiver

- 1) Abbott ID Now (15")
- 2) Cepheid GeneXpert (50")
[PPA: 97.8%; NPA: 95.6%]



FDA EUA Approved POC Tests CLIA Certificate of Waiver

- 1) Quidel Sofia
- 2) BD Veritor
- 3) LumiraDX
- 4) Abbott BinaxNOW

Currently Available Antigen Tests (APHL)

Test Name	Separate Instrument Required	Specimen Types	Time to Result	Test Performance*	More Information
Quidel Sofia 2 SARS Antigen FIA	Yes Sofia 2 FIA Analyzer	NP or Nasal Swabs Directly; Specimens should be collected within 5 days of symptom onset VTM is not recommended	15-30 minutes	PPA: 96.7%% NPA 100%	IFU HCP
BD Veritor System for Rapid Detection of SARS-CoV-2	Yes BD Veritor Plus Analyzer	Nasal Swabs (supplied with kit) Directly Only	15 minutes	PPA: 85% NPA: 100%	IFU HCP
LumiraDx SARS-Cov-2 Ag Test	Yes LumiraDX Instrument	Nasal Swab; Should be collected within the first 12 days of symptom onset	12 minutes	PPA: 97.6% NPA: 96.6%	IFU HCP
Abbott BinaxNOW COVID-19 Ag CARD	No	Direct nasal swab; collected within 7 days of symptom onset	15 minutes	PPA: 97.1% NPA: 98.5%	IFU HCP

PPA: Percent Positive Agreement | **NPA:** Negative Percent Agreement

FDA EUA Approved Saliva Tests

Company	Test Name	Type	Instrument/Platform	IFU/EUA	Sample Types	of
<input type="text" value="Filter Company"/>	<input type="text" value="Filter Test Name"/>	All	All		saliva	
Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect	Lab-performed test or service	Bio-Rad CFX96 ABI 7500	IFU/EUA	saliva	
DxTery Diagnostics, Inc.	DxTery SARS-CoV-2 RT-PCR Test	Lab-performed test or service	ThermoFisher ViiA7	IFU/EUA	saliva	
Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT-qPCR Test	Lab-performed test or service	Bio-Rad CFX384	IFU/EUA	saliva	
P23 Labs, LLC	P23 Labs TaqPath SARS-CoV-2 Assay	Lab-performed test or service	ThermoFisher QuantStudio 5	IFU/EUA	nasopharyngeal swab nasal swab nasal wash oropharyngeal swab saliva bronchoalveolar lavage	
Access Genetics, LLC	OraRisk COVID-19 RT-PCR	Lab-performed test or service	Roche LightCycler	IFU/EUA	nasopharyngeal swab nasal swab saliva	
DxTery Diagnostics, Inc.	DxTery SARS-CoV-2 RT PCR CE Test	Lab-performed test or service	ABI 3500xL Dx Genetic Analyzer	IFU/EUA	saliva	
Fluidigm Corporation	Advanta Dx SARS-CoV-2 RT-PCR Assay	Molecular Test Kit	Biomark HD	IFU/EUA	saliva	
Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay	Lab-performed test or service	ThermoFisher QuantStudio 5 ThermoFisher ViiA7	IFU/EUA	nasopharyngeal swab nasal swab oropharyngeal swab saliva bronchoalveolar lavage	
Clinical Reference Laboratory, Inc.	CRL Rapid Response	Lab-performed test or service	Bio-Rad CFX96	IFU/EUA	saliva	

Source: [COVID-19 Testing Comparison Database](#)

Regulatory and Reporting Requirements

- CLIA Certificate of Waiver
 - [CLIA Certificate of Waiver Registration Information](#)
 - Laboratory Field Services (LFS) process within 10 days
- Reporting Requirements
 - All Results: CA DPH CalREDIE
 - [CalREDIE Manual Lab Reporting Quick Start Guide](#)
 - [CalREDIE Manual Lab Reporting Account Authorization Form](#)
 - Positive Results: Alameda County PHD
 - [Confidential Morbidity Report \(MMR\)](#)

Resources

- [ALCO Free Testing Site](#)
- [CDPH Free Testing Site](#)
- [Labs to Contract for Testing](#)
- [COVID-19 Testing Comparison Database](#)
- [CMS Enforcement Discretion for POC Antigen Tests Used in Asymptomatic Individuals](#)
- [CDC Interim Guidance for Rapid Antigen Testing for SARS-CoV-2](#)

Thank You

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Question & Answer Time

