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
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
Alameda County Public Health Department

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
  

• 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
Everybody has a plan

“Everybody has a plan until they get punched in the face.”

Mike Tyson
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
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 (>100° F) or Chills
- Cough
- Shortness of Breath
- Difficulty Breathing
- Fatigue
- Muscle or Body Aches
- Headache
- New Loss of Taste or Smell
- Sore Throat
- Congestion/Runny Nose
- Nausea or Vomiting
- Diarrhea
- Shortness of Breath
- Headache
- New Loss of Taste or Smell
- Sore Throat
- Congestion/Runny Nose
- Nausea or Vomiting
- 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
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
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.
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
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
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

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

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Clinical Dental Director, Office of Dental Health
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Preprocedural COVID-19 Testing

Louis Girling, Jr., MD, FAAP
COVID-19 Response Clinical Guidance Lead Physician
Thursday, September 24, 2020
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
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


• 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
Alameda County COVID-19 Testing Dashboard

Alameda County Total

Tests: 513,049
Tests per 1,000 persons: 311.1
Positives: 24,448
Percentage Positive: 4.8%

Berkeley LHJ

Tests: 45,378
Tests per 1,000 persons: 380.8
Positives: 749
Percentage Positive: 1.7%

Alameda County LHJ

Tests: 467,671
Tests per 1,000 persons: 305.7
Positives: 23,699
Percentage Positive: 5.1%

Alameda County Total Testing Rate per 1,000

- Hispanic/Latino: 201.1
- Asian: 104.9
- African American: 183.0
- White: 181.3
- Pacific Islander: 147.8
- Native American: 25.7
- Multirace: 145.3
- Overall Known: 311.1

Alameda County Total Rolling 7-Day % Positive Tests

- Mar 2020: 20.0
- Apr 2020: 9.3
- May 2020: 9.2
- Jun 2020: 6.2
- Jul 2020: 3.4
- Aug 2020: 2.5
- Sep 2020: 2.0

Alameda County Total Tests, Rolling 7-Day Average

- Mar 2020: 1,000
- Apr 2020: 261.0
- May 2020: 619.0
- Jun 2020: 1,966.0
- Jul 2020: 4,186.0
- Aug 2020: 4,520.0
- Sep 2020: 4,797.0
# State Data Monitoring Metrics

<table>
<thead>
<tr>
<th>Measure</th>
<th>Widespread Tier 1</th>
<th>Substantial Tier 2</th>
<th>Moderate Tier 3</th>
<th>Minimal Tier 4</th>
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<tbody>
<tr>
<td>Adjusted Case Rate for Tier Assignment**</td>
<td>&gt;7</td>
<td>4-7</td>
<td>1-3.9</td>
<td>&lt;1</td>
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<tr>
<td>(Rate per 100,000 population* excluding prison cases^, 7 day average with 7 day lag)</td>
<td></td>
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<tr>
<td>Testing Positivity^</td>
<td>&gt;8%</td>
<td>5-8%</td>
<td>2-4.9%</td>
<td>&lt;2%</td>
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<tr>
<td>(Excluding prison cases^, 7 day average with 7 day lag)</td>
<td></td>
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</tbody>
</table>
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
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
Louis.Girling@acgov.org
Considerations for Establishing COVID-19 Testing within Your Practice

Kristina Hsieh DrPH, HCLD (ABB)
Director of Public Health Laboratory Services
September 24, 2020
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%]

**Source:** Chemical & Engineering News (Periodic Graphics)
## Currently Available Antigen Tests (APHL)

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Separate Instrument Required</th>
<th>Specimen Types</th>
<th>Time to Result</th>
<th>Test Performance*</th>
<th>More Information</th>
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<tbody>
<tr>
<td>Quidel Sofia 2 SARS Antigen FIA</td>
<td>Yes</td>
<td>NP or Nasal Swabs Directly; Specimens should be collected within 5 days of symptom onset VTM is not recommended</td>
<td>15-30 minutes</td>
<td>PPA: 96.7%; NPA 100%</td>
<td>IFU HCP</td>
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<tr>
<td>BD Veritor System for Rapid Detection of SARS-CoV-2</td>
<td>Yes</td>
<td>Nasal Swabs (supplied with kit) Directly Only</td>
<td>15 minutes</td>
<td>PPA: 85%; NPA: 100%</td>
<td>IFU HCP</td>
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<tr>
<td>LumiraDx SARS-CoV-2 Ag Test</td>
<td>Yes</td>
<td>Nasal Swab; Should be collected within the first 12 days of symptom onset</td>
<td>12 minutes</td>
<td>PPA: 97.6%; NPA: 96.6%</td>
<td>IFU HCP</td>
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<tr>
<td>Abbott BinaxNOW COVID-19 Ag CARD</td>
<td>No</td>
<td>Direct nasal swab; collected within 7 days of symptom onset</td>
<td>15 minutes</td>
<td>PPA: 97.1%; NPA: 98.5%</td>
<td>IFU HCP</td>
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*PPA: Percent Positive Agreement | NPA: Negative Percent Agreement
## FDA EUA Approved Saliva Tests

<table>
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<tr>
<th>Company</th>
<th>Test Name</th>
<th>Type</th>
<th>Instrument/Platform</th>
<th>IFU/EUA</th>
<th>Sample Types</th>
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<tbody>
<tr>
<td>Yale School of Public Health, Department of Epidemiology of Microbial Diseases</td>
<td>SalivaDirect</td>
<td>Lab-performed test or service</td>
<td>Bio-Rad CFX96 ABI 7500</td>
<td>IFU/EUA</td>
<td>saliva</td>
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<tr>
<td>DxTenty Diagnostics, Inc.</td>
<td>DxTenty SARS-CoV-2 RT-PCR Test</td>
<td>Lab-performed test or service</td>
<td>ThermoFisher VIA7</td>
<td>IFU/EUA</td>
<td>saliva</td>
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<tr>
<td>Phosphorus Diagnostics LLC</td>
<td>Phosphorus COVID-19 RT-nPCR Test</td>
<td>Lab-performed test or service</td>
<td>Bio-Rad CFX384</td>
<td>IFU/EUA</td>
<td>saliva</td>
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<tr>
<td>P23 Labs, LLC</td>
<td>P23 Labs TanPath SARS-CoV-2 Assay</td>
<td>Lab-performed test or service</td>
<td>ThermoFisher QuantStudio 5</td>
<td>IFU/EUA</td>
<td>nasopharyngeal swab nasal swab nasopharyngeal swab saliva bronchoalveolar lavage</td>
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<tr>
<td>Access Genetics, LLC</td>
<td>OraRisk COVID-19 RT-PCR</td>
<td>Lab-performed test or service</td>
<td>Roche LightCycler</td>
<td>IFU/EUA</td>
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<td>DxTenty Diagnostics, Inc.</td>
<td>DxTenty SARS-CoV-2 RT-PCR CE Test</td>
<td>Lab-performed test or service</td>
<td>ABI 3500xl Dx Genetic Analyzer</td>
<td>IFU/EUA</td>
<td>saliva</td>
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<td>Fluidigm Corporation</td>
<td>Advanta Dx SARS-CoV-2 RT-PCR Assay</td>
<td>Molecular Test Kit</td>
<td>Biomark HD</td>
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<td>Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University</td>
<td>Rutgers Clinical Genomics Laboratory TanPath SARS-CoV-2 Assay</td>
<td>Lab-performed test or service</td>
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<td>Clinical Reference Laboratory, Inc.</td>
<td>CRL Rapid Response</td>
<td>Lab-performed test or service</td>
<td>Bio-Rad CFX96</td>
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<td>saliva</td>
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Source: [COVID-19 Testing Comparison Database](https://www.path.org/covid19testingdatabase)
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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Kristina.Hsieh@acgov.org
Question & Answer Time