Guidance on the Use of COVID-19 Antigen Testing in Skilled Nursing Facilities

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Disclosures

There is no commercial support for today's webinar

Neither the speakers nor planners for today's webinar have disclosed any financial interests related to the content of the meeting

This webinar is meant for healthcare facilities and is off the record and reporters should log off now.

DISCLAIMER

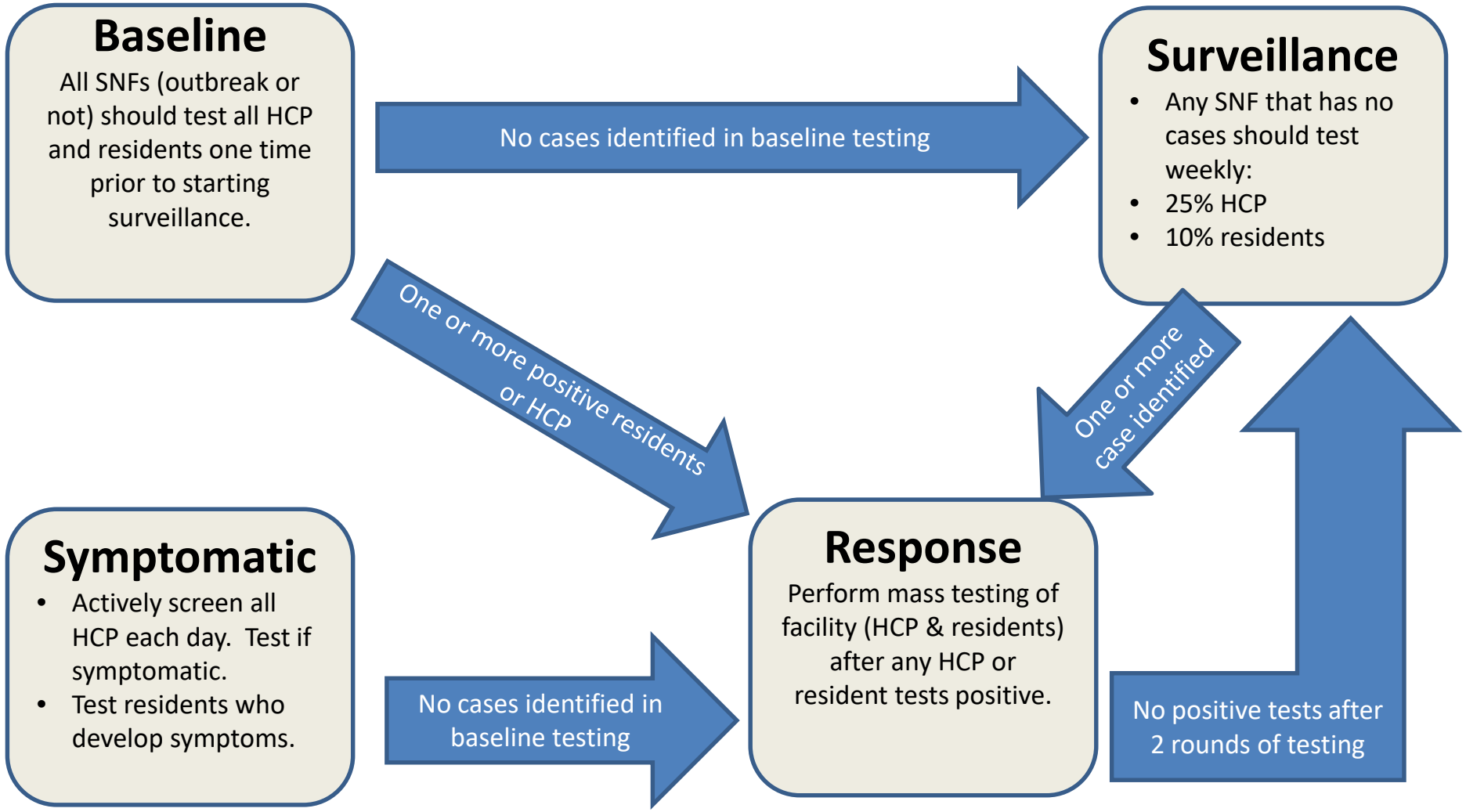
- This is a rapidly evolving situation so the information being presented is current as of today (8/7/20) so we highly recommend that if you have questions after today you utilize the resources that we will review at the end of this presentation.

COVID Testing Update

CDPH AFL

State of California—Health and Human Services Agency
California Department of Public Health

- AFL 20-53 (5/22/20)
  - Testing by SNF, TAT ≤48 hours
  - Baseline, surveillance, response-driven testing
  - Quarantine all admissions/readmissions & test day 0 & 14



Testing Strategy for Nursing Homes

Testing details

- LACDPH/CDPH do not recommend repeated testing for patients who have previously tested positive x 90 days.
- LACDPH and LA City have completed baseline testing for all SNFs
- Ongoing testing is required of SNFs per CDPH.
  – CDPH to provide additional guidance on funding.
- Labs must have quick TAT (48 hours or less)*
- All new admissions and re-admissions (not previously infected w COVID) require testing on admission→14 day Quarantine→negative test.

* Aug 6 Q and A: Acceptable TOT for molecular test results is 3-5 days

COVID Testing

County of Los Angeles Public Health

	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
Also known as...	Diagnostic test, viral test, molecular test, nucleic acid amplification test (NAAT), RT-PCR test, LAMP test	Rapid diagnostic test (Some molecular tests are also rapid tests.)	Serological test, serology, blood test, serology test
How the sample is taken...	Nasal or throat swab (most tests) Saliva (a few tests)	Nasal or throat swab	Finger stick or blood draw
How long it takes to get results...	Same day (some locations) or up to a week	One hour or less	Same day (many locations) or 1-3 days
Is another test needed...	This test is typically highly accurate and usually does not need to be repeated.	Positive results are usually highly accurate but negative results may need to be confirmed with a molecular test.	Sometimes a second antibody test is needed for accurate results.
What it shows...	Diagnoses active coronavirus infection	Diagnoses active coronavirus infection	Shows if you've been infected by coronavirus in the past
What it can't do...	Show if you ever had COVID-19 or were infected with the coronavirus in the past	Definitively rule out active coronavirus infection. Antigen tests are more likely to miss an active coronavirus infection compared to molecular tests. Your health care provider may order a molecular test if your antigen test shows a negative result but you have symptoms of COVID-19.	Diagnose active coronavirus infection at the time of the test or show that you do not have COVID-19

www.fda.gov 1 July 2020

https://www.fda.gov/media/140161/download

Indications for Testing

- Individuals with signs or symptoms consistent with COVID-19
- Response testing – testing all staff and residents not already known to be infected <90 days prior in a facility with other identified COVID-19 cases within the previous 2 weeks; done for the purpose of outbreak management
- Surveillance testing – testing a sample of staff and residents not already known to be infected <90 days prior in a facility without any COVID-19 cases within the previous 2 weeks; done for the purpose of early detection of COVID-19 in a facility

Using Viral Antigen Testing in Skilled Nursing Facilities

- The use of POC COVID-19 antigen testing in SNFs is still being defined
- LAC DPH interim guidance is currently being developed
- The new guidance takes into account:
  - the ease of use
  - rapid turn-around
  - ready availability of antigen testing while taking into consideration the lower sensitivity of this testing type
- These factors are balanced against the greater sensitivity of the molecular testing, current challenges with test availability and TOT with this test type

Antigen testing

- Emergency Use Authorization approved tests
  - Becton Dickenson (BD) Veritor™ Plus System (chromatographic immunoassay)
  - Sofia Sars-COV-2 testing (Quidel) (fluorescence immunoassay)
- Point of care rapid tests with a TOT of 15-30 minutes
- Lateral flow technology
- Clinical use of antigen tests still being defined
  - Higher false negative rate
  - Negative tests should be confirmed with PCR
- All POC tests (pos and neg) should be reported to LA County DPH

- **FOR IMMEDIATE RELEASE**
  July 14, 2020
- **Announces Initiative for More and Faster COVID-19 Testing in Nursing Homes***
- Large-scale procurement of U.S. Food and Drug Administration (FDA) -authorized rapid point-of-care diagnostic test instruments and tests to be distributed to nursing homes in COVID-19 hotspot geographic areas with the United States.
- One-time procurement of devices and tests targeted to facilitate on-site testing among nursing home residents and staff.
  - to augment their current capacity for coronavirus testing, bolstering their response and helping to prevent the spread of COVID-19.

***Nursing homes refer to facilities that are certified as a Medicare Skilled Nursing Facility (SNF) and/or] Medicaid Nursing Facility (NF), otherwise referred to a Long Term Care Facility or nursing home.**

Point of Care SARS Co-V Antigen Testing

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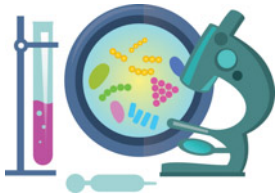
Point of Care Testing Devices

County of Los Angeles Public Health

Phase I: 636 nursing homes nationwide received the first batch of COVID-19 Point of Care Test Devices.



- California: 231 SNFs identified
- Los Angeles County: 209 SNFs identified (32.8% of Phase I)

Criteria for Phase I
CLIA Certificate of Waiver
3 or more confirmed/suspected cases in last 7 days
At least 1 new case in last 7 days (0 previously)
Inadequate access to testing in the last 7 days
At least 1 new resident death in last 7 days
At least 1 new confirmed or suspected case for staff

Upon receipt, the instrument becomes the property of the nursing home and can be used in accordance with the conditions of authorization for the test.

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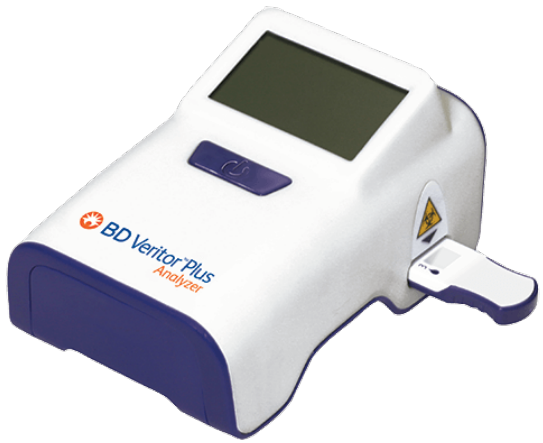
Point of Care Devices

- Devices will be sent directly to Phase I SNFs the week of July 30
- 100% SNFs before end of October
- Most SNFs will receive 1 device & approx. 325 tests (depending on capacity/census)
- Manufacturers will provide hard-copy training materials to SNF staff; online options available on manufacturer websites

BD Veritor Plus system



Quidel Sofia 2 Instrument

https://togetheragain.quidel.com

NOTE: After initial shipment of instruments and tests, nursing homes will be responsible for procuring their own tests directly from the manufacturer or medical device distributor.

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Safety Precautions

What safety precautions are required when performing these tests:

- Use recommended PPE, including N95 or higher-level respirator
- Use device in location associated with current CLIA certificate
- Perform site-specific and activity specific risk assessment
- Train staff on proper use of the instrument to minimize exposure
- Use standard precautions when handling clinical specimens
- Decontaminate instrument after each run by using EPA-approved disinfectant.

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Antigen Tests

Antigen diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs.

- **Negative results should be treated as presumptive**
- **Negative results should not be used as the sole basis for treatment or patient management decisions**
- **Negative results should be considered in the context of a patient's recent exposures, history and symptoms**
- **Confirming negative results using an alternate form of testing is recommended.**

For patients with known risk factors, positive results from antigen tests can be considered confirmatory and used for diagnostic purposes.

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Testing & Reporting

Each test takes about 20 minutes to perform from start to finish. However, it is possible to run tests in an assembly line fashion to test 20-30 samples per hour. To use this strategy, the start time for each test is staggered. At the end of the test incubation period, each test is read one by one every few minutes.

All laboratories/testing sites must have a CLIA Certificate and report the results of the COVID-19 tests that they conduct to the appropriate Federal, State, and/or local public health agencies.

Laboratories/testing sites must report data for ALL testing completed, for each individual tested, according to Federal, State and/or local public health orders.

If the test does not flow correctly, the instrument will indicate that the result is invalid. Should this occur, review the procedure and repeat the test with a new patient sample and a new test kit. Do not report invalid results.

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Physician Orders, Storage

These are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance.

Note: MD orders for COVID-19 testing waived.

Reagents and instruments must be stored at room temperature, out of direct sunlight, when used for testing. DO NOT FREEZE.

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Early Feedback

County of Los Angeles Public Health

Initial outreach to 25 SNFs on the Phase I list. Here is a sample of responses to the Point of Care testing instruments:

"We are using the devices, but we don't think they are accurate. All 5 of our confirmed cases tested negative. We reported to CMS and they are sending guidance to retest."

We are waiting for CMS to provide additional guidance."

"We are on the list to receive the devices, but nothing has arrived yet."

"We received the devices but have not received guidance or training."

"We are awaiting guidance from public health."

"Public Health said we should use PCR based tests."

"We were unaware of the program."

Benefits of Antigen Testing

Besides the quicker turnaround time, one of the benefits of antigen testing is sensitivity. The sensitivity is reported to be around 80%. Those who test positive for COVID-19 through point of care testing can be confident they are truly positive.

Those that test negative may want to confirm their results with a standard polymerase chain reaction (PCR) test.

Could a SNF use the point-of-care tests for family members to increase visitation at the SNF? **YES**
Can the point-of-care test totally replace traditional PCR and blood-serum tests? **NO**

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Testing Guidelines

Nursing homes must use tests that offer at least 95% sensitivity, meaning that the tests can't miss more than 5% of people that have the disease. But the antigen tests offered by the federal government only offer about 80% sensitivity. So unless state officials change the rules, California's skilled nursing facilities can't use the federal kits to screen their residents. The state's nursing home industry group has asked the public health agency for more clarification but had received no answer by Friday (July 31), according to Craig Cornett, CEO and president of the California Association of Health Facilities.

CDPH

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State of California—Health and Human Services Agency
California Department of Public Health

GAVIN NEWSOM
Governor

July 31, 2020

AFL 20-53.2

TO: Skilled Nursing Facilities

SUBJECT: Coronavirus Disease 2019 (COVID-19) Mitigation Plan Recommendations for Testing of Health Care Personnel (HCP) and Residents at Skilled Nursing Facilities (SNF)
(This AFL supersedes AFL 20-53.1)

CDPH recommends SNFs include testing strategies informed by the CDC recommendations in their COVID-19 Mitigation plans. This plan should be developed in conjunction with CDPH and their local health department and include:

- An arrangement with laboratories to process tests. The test used should be an authorized nucleic acid or antigen detection assay for SARS-CoV-2 virus used as recommended for testing in nursing homes by CDC, with results obtained rapidly (e.g., within 48 hours). **Antibody test results should not be used to diagnose someone with an active SARS-CoV-2 (the virus that causes COVID-19) infection. The Department of Health and Human Services recently announced that it will begin providing nursing homes with a Point of Care (POC) rapid response testing instrument to bolster each facility's ability to prevent the spread of COVID-19.**

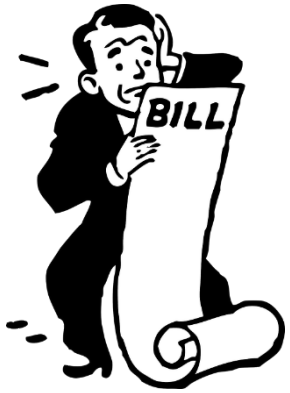
Who will pay for this?

COUNTY OF LOS ANGELES Public Health

COVID CODES

Code	Description	DOS effective	Medicare Allowable	Type of test
U0001	2019-NCOV DIAGNOSTIC P	2/4/2020	Carrier APX $32	Viral
U0002 (QW)	COVID-19 LAB TEST NON-CDC	2/4/2020	Carrier APX $52	Viral
U0003	COV-19 AMP PRB HGH THRUPUT	4/14/2020	$100.00	Viral
U0004	COV-19 TEST NON-CDC HGH THRU	4/14/2020	$100.00	Viral
87635 (QW)	SARS-COV-2 COVID-19 AMP PRB	3/13/2020	Same as U0002	Viral
87426 (QW?)	CORONAVIRUS AG IA	6/25/2020	TBD	Viral
86328	IA NFCT AB SARSCOV2 COVID19	4/10/2020	42.13	Antibody
86769	SARS-COV-2 COVID-19 ANTIBODY	4/10/2020	45.23	Antibody

G2023*	Specimen collect COVID-19	3/1/2020	$23.46	Specimen Collection
G2024*	Spec collect SNF/Lab COVID-19	3/1/2020	$25.46	Specimen Collection



Insurance Coverage	Guidance
Managed Medi-Cal	PPG/IPA risk vs Health Plan risk – member specific
Medicare A	Tests and specimen collection are bundled; If resident not covered under Part A stay, lab will bill Medicare B
Medicare B	Lab will bill Medicare B; or bill SNF and SNF bills Medicare B
Medicare Adv.	Must not charge cost sharing or apply prior auth requirements

LA County Interim Guidelines

	Testing strategy	Response
TIER 1 **PCR testing is easily accessible and with a turn-around time is <48 hours. Antigen testing may be used as a back-up strategy if PCR testing is unavailable.**		
	Standard PCR testing per recommendations[1]	Isolate/quarantine/cohort per recommendations.
TIER 2 **PCR testing is available, but with turn-around time >48 hours[2,3].**		
Symptomatic resident	POC Ag test positive → no additional testing	Isolate (Red zone).
	POC Ag test negative → confirm with PCR	Quarantine (Yellow zone) pending PCR confirmation → red zone if PCR positive, green zone if negative (requires 2 negative PCRs 24 hrs apart).
Asymptomatic resident	POC Ag test positive → confirm with PCR	Quarantine (Yellow zone) pending PCR confirmation → Red zone if positive, Green zone if PCR negative.
	POC Ag test negative → Confirm with PCR	Observe in green zone → Move to red zone if PCR positive.
Symptomatic staff	POC Ag test positive → no additional testing	Restrict from working for 10 days or 24 hours.
	POC Ag test negative → confirm with PCR	Restrict from work pending PCR result → restrict if positive, restrict until symptoms resolve if negative (requires 2 negative PCRs 24 hrs apart).
Asymptomatic staff	POC Ag test positive → confirm with PCR	Restrict from work for 10 days after test result.
	POC Ag test negative → Confirm with PCR	No work restriction → restrict if PCR positive.

1. http://publichealth.lacounty.gov/acd/docs/nCoVLTCGuide.pdf.
2. If PCR testing is insufficient to meet testing needs for all staff and residents, then prioritize residents for PCR testing.
3. Contact LAC DPH (213) 240-7941 if there is no commercial PCR testing available. DHS reference guide or the California Testing Taskforce to find a lab

Key Resources

- http://publichealth.lacounty.gov/media/coronavirus/
- https://www.cdph.ca.gov/programs/cid/dcdc/pages/immunization/ncov2019.aspx
- https://www.cdc.gov/coronavirus/2019-nCoV/index.html
- https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19
- https://www.hhs.gov/coronavirus/index.html
- https://www.cms.gov/About-CMS/Agency-Information/OMH/resource-center/COVID-19-Resources
- https://www.idsociety.org/public-health/COVID-19-Resource-Center/

Questions