

COVID-19 PROTOCOL PHASE IV



TESTING RESIDENTS AND STAFF
ACTIVE CASE & RECOVERY



Policy and Procedure

Title: COVID-19 Testing

Policy

To conduct COVID-19 rapid testing according to manufacture instructions.

Procedure

When to Test

1. Refer to the attached 'When to Test for COVID-19' table for testing parameters
2. Prior to testing a consent form must be completed (attached)
3. Once the individual has been deemed appropriate for testing and a signed consent has been received the Infection Preventionist nurse or designated trained nurse will administer test.

Testing Procedure

1. Bring all Test Devices, reagents and samples to room temperature (20-25 C) before testing.
2. Gather necessary supplies to complete testing
 - A. Testing kit
 - B. Gloves
 - C. Lancet
 - D. Alcohol swab
3. Apply PPE
4. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within ten minutes.
5. Place the test device on a clean and level surface.
6. Use the alcohol swab to disinfect the testers fingertip prior to taking the blood sample
7. Gently pinch the tester's fingertip and activate the lancet by pressing device body firmly against the testing site.
8. Gently apply intermittent pressure near the puncture site to obtain required blood volume.
9. With the 5 µL mini plastic dropper provided, draw serum specimen to exceed the specimen line as and then transfer drawn serum specimen into the sample well (S).
10. Immediately add 2 drops of sample buffer to the buffer well (B) in a vertical fashion. Take care to avoid air bubbles.
11. Results should be interpreted in 3 minutes.
 - A. Any interpretation after 10 minutes would be deemed invalid

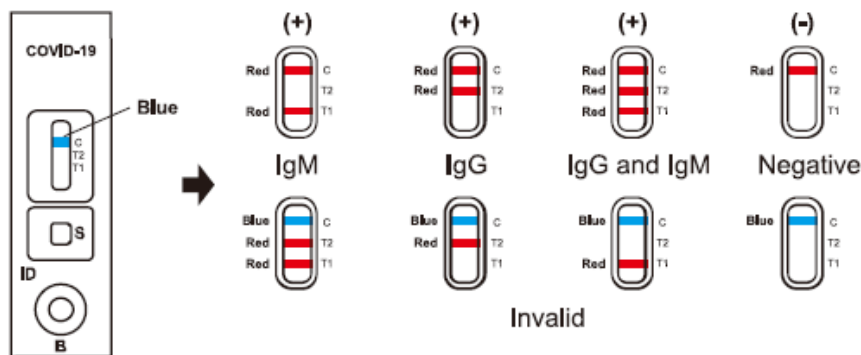
Visual demonstration may be viewed at:

<https://aytubio.com/covid-19-instructions-video/>



Interrupting Results

1. **NEGATIVE:** The colored line in the control line region (C) changes from blue to red. No line appears in the test line regions T1 or T2. The result is negative.
2. **IgM POSITIVE:** The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region T1. The result is anti-COVID-19 IgM positive.
3. **IgG POSITIVE:** The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region T2. The result is anti-COVID-19 IgG positive.
4. **IgG and IgM POSITIVE:** The colored line in the control line region (C) changes from blue to red, and two-colored lines appear in test line regions T1 and T2. The result is anti-COVID-19 IgM and IgG positive.



Invalid Test Results

1. Control line is still completely or partially blue. The test is invalid since the Presence of a blue control band indicates the test procedure was performed improperly or that deterioration of reagents has occurred.
2. If any result is difficult to interpret, the test should be repeated with the same sample to eliminate the potential for error. Obtain a new sample and retest when the original sample repeatedly produces unreadable results.
3. Review the procedure and repeat the test with a new test cassette.

Receiving a Negative Result

1. Record testing information on COVID-19 Test Log (attached)
2. If a negative result is received the resident/ employee will need to be tested again if 5 days if symptoms do not subside.
3. If the resident being tested is located outside of the observation/contamination unit (general population) they, and any roommate, are to isolate in place for 15 days.
 - A. A resident is only to be moved to the observation/contamination unit if the second test reveals they are positive for COVID-19
4. A resident who is being tested and is already in the observation/contamination unit is to remain inside of the unit for the full 15 day period even if negative test results are received.



Receiving a Positive Result

1. Refer to 'Receiving a Positive COVID-19 Test Result' policy and procedure

Attachments: When to Test for COVID-19
COVID-19 Testing Consent
COVID-19 Test Log



When to Test for COVID-19

Resident in General Population	Roommate of a Resident Who Tested Positive	Resident in the OBS / Contamination Unit	Employee
<p>Resident has:</p> <ul style="list-style-type: none"> ✓ Visited an ER in the last 15 days ✓ Visited or been admitted to the hospital in the last 15 days ✓ Visited any office/facility outside of the SNF <ul style="list-style-type: none"> • Dr. visits • Chemotherapy • Dialysis <p>If yes to any of the above: Does the resident have any of the following symptoms?</p> <ul style="list-style-type: none"> ✓ Drop in O2 sat ✓ Cough ✓ Shortness of breath ✓ Sore throat ✓ Temp. of 99.5 or higher ✓ Any symptoms that cannot be related to allergies or asthma <p><u>If yes, conduct a test</u></p>	<p><u>Test immediately. Symptoms do not have to be present</u></p> <p>Test again if:</p> <p>Symptoms appear during the observation period</p> <ul style="list-style-type: none"> ✓ Drop in O2 sat ✓ Cough ✓ Shortness of breath ✓ Sore throat ✓ Temp. of 99.5 or higher ✓ Any symptoms that cannot be related to allergies or asthma 	<p>Does the resident have any of the following symptoms?</p> <ul style="list-style-type: none"> ✓ Drop in O2 sat ✓ Cough ✓ Shortness of breath ✓ Sore throat ✓ Temp. of 99.5 or higher ✓ Any symptoms that cannot be related to allergies or asthma <p>Or</p> <ul style="list-style-type: none"> ✓ Shared a room with an individual who tested positive <p><u>If yes, conduct a test</u></p>	<p>Does the employee have any of the following symptoms?</p> <ul style="list-style-type: none"> ✓ Drop in O2 sat ✓ Cough ✓ Shortness of breath ✓ Sore throat ✓ Temp. of 99.5 or higher ✓ Any symptoms that cannot be related to allergies or asthma <p><u>If yes, conduct a test</u></p>



COVID-19 Testing Consent

I hereby agree to submit a small blood sample, collected through a finger stick, to be tested for COVID-19. I understand that there are no side effects caused by the testing procedure other than a small amount of pain at the testing site. I understand, as with any medical test, there is a chance for a false positive or a false negative result. In the event of a positive result, I understand that I will be referred for Nasopharyngeal / Oropharyngeal testing.

Name of Person Tested (Print)

- Resident Verbal Consent Given – Must be witnessed by two nurses
 Employee

Resident / Responsible Party/ Employee Signature

Date

Time

Witness

Date

Time

Witness

Date

Time



COVID-19 Testing Consent

I hereby agree to a Nasopharyngeal / Oropharyngeal COVID-19 test. I understand that the test is conducted by gently inserting a small swab with a soft tip through the nostril(s) to the back of the nose to collect secretions. I understand that side effects to this testing procedure include gagging, pressure, or slight discomfort.

Name of Person Tested (Print)

- Resident Verbal Consent Given – Must be witnessed by two nurses
 Employee

Resident / Responsible Party/ Employee Signature

Date

Time

Witness

Date

Time

Witness

Date

Time



Policy and Procedure

Title: Receiving a Positive COVID-19 Result

Policy

To ensure the proper precautions and steps are taken, according to CDC guidance, when a resident or employee tests positive for COVID-19.

Procedure

Residents

1. Record testing information on COVID-19 Test Log (attached)
2. Notify the following:
 - A. Regional team and CCO
 - i. CCO/Designee will notify vendors to get increased PPE and other needed supplies
 - B. Resident and/or their representative
 - C. State survey agency – File state reportable event (FRI)
 - D. Local and State Health Department
 - E. Primary physician for the resident
 - F. The following individuals must be notified by **5pm on the next calendar day**
 - i. All employees working in the facility
 - ii. Residents
 - iii. Families/ Responsible party of all residents (see attached letter)
3. Privacy curtain must be pulled between roommates immediately
4. Resident is to be moved the Containment Unit – Cohort appropriately (Positive residents must be placed alone or with another positive resident)
 - A. Staff dressed in full PPE will place the resident's personal belongings in a plastic bag that is to be tied and transported to the Contamination Unit.
 - i. N95 respirator are only to be used when active case occurs -Refer to Mask Comparison (attached)
 - B. Resident must be wearing a N95 respirator or mask that is available during transfer
 - C. Housekeeping will enter 3 hours after the resident has been moved to the Contamination Unit to clean all surfaces (including roommate's surfaces)
5. Roommate is to be tested immediately. If results are negative a second test will be administered if a symptoms are observed.
 - A. Resident must be observed for 15 days prior to receiving a new roommate.
6. Ensure stop sign is posted on outside of door (type of precautions & Donning/Doffing instructions will be stored with PPE)
7. Ensure PPE station is ready – refer to AHCA and CDC PPE Guidance on use of masks, gowns, and eye protection to conserve supplies
 - A. Utilize daily logs to identify how much PPE is being used



8. Begin tracking the staff going in and out of room (use Staff Attestation Log)
9. Utilize the COVID-19 Tracking/Tracing spreadsheet to determine who was exposed
 - A. Located on the (P:) drive (Clinical Programs/Infection Control Manual/ FLU-COVID-19 Outbreak Plan/COVID-19 Tracking)
 - B. Send a copy to Local and State Health Departments
10. Monitor vital signs and initiate COVID-19 screening (attached) twice a day on exposed residents. (to be determined by IP Nurse and Nurse Leadership—contact RCD with questions)
11. If COVID-19 positive resident must leave the room, ensure they are wearing a mask prior to leaving.
12. Have resident cover mouth with barrier/ mask while team members are in the room providing cares
13. Any aerosol nebulizer treatment needs to be ordered as an inhaler
14. ONLY in case of emergency call 911 and notify EMS that this is a COVID-19 positive resident (breathing or circulatory issues) –Not every transport service will be equipped to manage – Health department will help facilitate.
15. Reeducate all staff on precautions and the plan moving forward with special emphasis on the staff that will be working with these residents
 - A. PPE
 - B. Hand Hygiene
 - C. Cleaning needs
 - D. Documentation
 - E. Isolation precautions
16. Have Healthcare Service Group supervisor/designee provide education to the nursing team to ensure proper cleaning techniques are being followed

Employee

1. Record testing information on COVID-19 Test Log (attached)
2. Contact the following:
 - A. Notify Regional team, CCO, and HR
 - B. Local and State Health Department
 - C. Notify state survey agency– File state reportable event (FRI)
3. Utilize the COVID-19 Tracking spreadsheet to determine who was exposed
 - A. Located on the (P:) drive (Clinical Programs/Infection Control Manual/ FLU-COVID-19 Outbreak Plan/COVID-19 Tracking)
 - B. Send a copy to Local and State Health Departments
4. Initiate COVID-19 screening (attached) to be completed twice a day on residents exposed to employee
5. All employees who had contact with the COVID-19 positive team member should initiate self-monitoring twice daily (including temperature)

Attachments: Letter to Family for a Positive Case (Facility specific letters located on the (P:) drive)
Mask Comparison
COVID-19 Screening (Located in PCC as a UDA)
COVID-19 Tracking Spreadsheet (located on the (P:) drive)

[Date]

To Our Residents and Family Members:

We know that you are concerned about the spread of COVID-19 (coronavirus) and how it may impact your loved one at our center. Please understand that making sure our patients and residents are cared for in a safe and healthy environment is our top priority.

From the onset of current COVID-19 crisis, we have been both diligent and proactive in our efforts to reduce the potential for an active COVID-19 case(s) within our center. Additionally, we have prepared for the scenario in which an active case is identified at our facility. This includes, among other things, establishing a designated observation unit for suspected or confirmed COVID-19 cases.

We want to inform you that we have received confirmation that an individual at our facility has been diagnosed with COVID-19. We are doing everything we can to ensure we stop the spread of COVID-19 within our center, including staying in very close communication with local and state health officials to ensure we are taking all the appropriate steps. We are not permitting visitors per the direction of the local health department.

We encourage you to call our center at the number listed below for updates on the status of your loved one. We understand that you are concerned about your loved one, but it is crucial that we restrict visitation to reduce the spread of this virus. We also understand that connecting with family members is incredibly important to our residents. Family members are encouraged to connect with their loved ones through video chat, calling, texting, or other social media formats.

We will contact you if your loved one is suspected or diagnosed with COVID-19. We need your help in battling COVID-19. Please visit the Centers for Disease Control and Prevention (CDC) website at www.cdc.gov to learn how you can help prevent the spread in our community.

We know this is a difficult time for everyone. We will continue to provide you with updates as they become available. Please know that we are strictly adhering to all directions from the local and state health department.

Thank you for your understanding and support. Should you have any questions, please contact our center at [Enter Phone Number].

Sincerely,

Administrator

Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes

Description

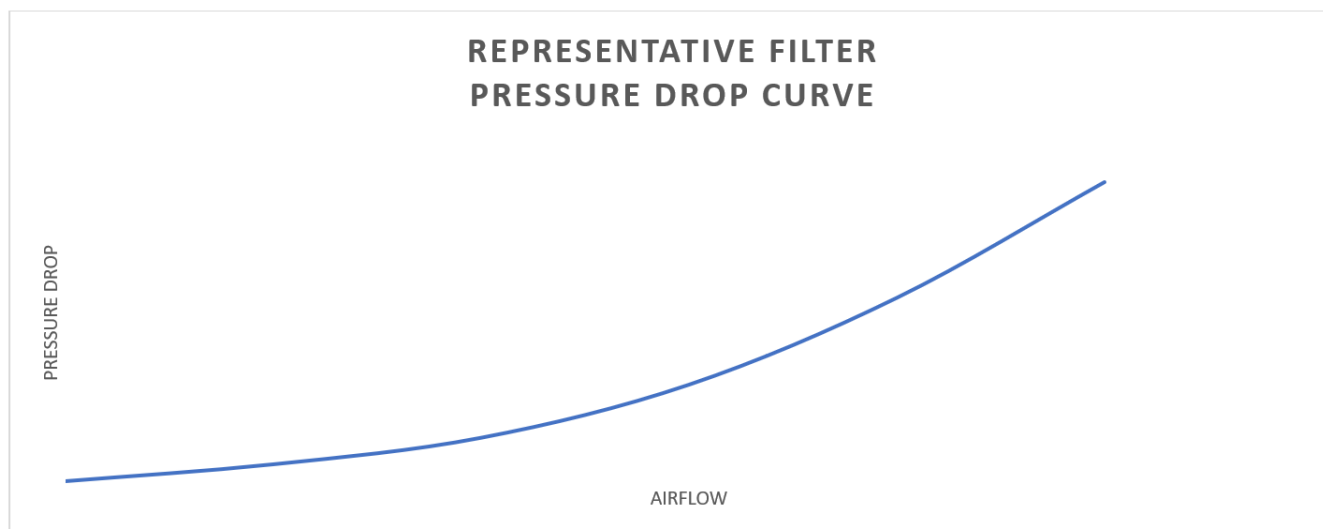
Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular standard. During pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an “N95, FFP2, or equivalent” respirator.

This document is only intended to help clarify some key similarities between such references, specifically to the following FFR performance standards:

- N95 (United States NIOSH-42CFR84)
- FFP2 (Europe EN 149-2001)
- KN95 (China GB2626-2006)
- P2 (Australia/New Zealand AS/NZA 1716:2012)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS (Japan JMHLW-Notification 214, 2018)

As shown in the following summary table, respirators certified as meeting these standards can be expected to function very similarly to one another, based on the performance requirements stated in the standards and confirmed during conformity testing.

One notable comparison point is the flow rates specified by these standards for the inhalation and exhalation resistance tests. Inhalation resistance testing flow rates range from 40 to 160L/min. Exhalation resistance testing flow rates range from 30 to 95 L/min. Some countries require testing to be performed at multiple flow rates, others at only the high or low end of those ranges. Although this appears to suggest that the standards’ requirements for breathing resistance (also called “pressure drop”) differ from each other, it’s important to understand that pressure drop across any filter will naturally be higher at higher flow rates and lower at lower flow rates. Given typical pressure curves for respirator filters, the standards’ various pressure drop requirements are actually quite similar. This chart shows a representative filter pressure drop curve. If one filter is tested at a high flow rate, the pressure drop performance will be relatively high. If that same filter is tested at a low flow rate, the pressure drop performance will be relatively low.



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Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DS FFRs as “equivalent” to US NIOSH N95 and European FFP2 respirators, for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols (e.g. viruses). However, prior to selecting a respirator, users should consult their local respiratory protection regulations and requirements or check with their local public health authorities for selection guidance.

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-20 06)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLW- Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO ₂ clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

Definitions

Filter performance – the filter is evaluated to measure the reduction in concentrations of specific aerosols in air that passes through the filter.

Test agent - the aerosol that is generated during the filter performance test.

Total inward leakage (TIL) – the amount of a specific aerosol that enters the tested respirator facepiece via both filter penetration and facesal leakage, while a wearer performs a series of exercises in a test chamber.

Inward leakage (IL)– the amount of a specific aerosol that enters the tested respirator facepiece, while a wearer performs a normal breathing for 3 minutes in a test chamber. The test aerosol size (count median diameter) is about 0.5 micro meter.

Pressure drop – the resistance air is subjected to as it moves through a medium, such as a respirator filter.

IMPORTANT: Always read and follow respirator user instructions.

Personal Safety Division
3M Center, Building 235-2W-70
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occupational use only.

In United States of America
Technical Service: 1-800-243-4630
Customer Service: 1-800-328-1667
3M.com/workersafety
In Canada
Technical Service: 1-800-267-4414
Customer Service: 1-800-364-3577
3M.ca/Safety

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COVID-19 Screening

Resident: _____ Date: _____

Signs and Symptoms:

If no vitals taken in last 8 hours, take new vitals and enter as new

Most Recent Temperature

Temp: _____

Route: _____

Date: _____ New

Most Recent O2 Sats

O2 Sat: _____

Method: _____

Date: _____ New

Most Recent Blood Pressure

BP: _____

Position: _____

Date: _____ New

Most Recent Pulse

Pulse: _____

Type: _____

Date: _____ New

Most Recent Respiration

Resp: _____

Date: _____ New

Does the patient/resident have new onset of a runny nose? Yes No

Does the patient/resident have new onset of a sore throat? Yes No Unable to Determine

Does the patient/resident have new onset of nasal congestion? Yes No Unable to Determine

Does the patient/resident have new onset of chest congestion? Yes No

Does the patient/resident have new onset of a cough? Yes No

Does the patient/resident have new onset or increase of shortness of breath? Yes No

Does the patient/resident have new onset of tachycardia? (more than 100 bpm) Yes No

Does the patient/resident have a fever (100.4* or greater)? Yes No

Does the patient/resident have new onset or worsening confusion? Yes No

Are there any other new symptoms present? Yes No

Other new symptoms: _____

Action:

If you answered 'Yes' to any of the questions above you **must** complete the SBAR and notify the physician and nursing leadership as these are indicators of COVID-19.

Nursing Note:



Policy and Procedure

Title: COVID-19 Recovery

Policy

To ensure a resident's safe discharge to facilities general population.

Procedure

Recovery Timeline

Median time from onset to clinical recovery for mild cases is approximately 2 weeks and is 3 to 6 weeks for patients with severe or critical disease.

Severity Definitions

Mild cases to moderate symptoms - non- Pneumonia, mild respiratory symptoms, fever, dry cough, fatigue, shortness of breath and headaches.

Severe cases - dyspnea, respiratory frequency greater than 30 per minute, blood oxygen saturation less than 93% (average age patient), and lung infiltrates in greater than 50% of lung field within 24-48 hours of becoming symptomatic. Time frame for onset of symptoms to severe status is approximately one week

Critical cases -respiratory failure, septic shock and multiple organ failure.

High Risk Residents

Any resident over 60 years with underlying conditions such as hypertension, diabetes, cardiovascular disease, chronic respiratory disease and cancer are consider to be high risk. Mortality increases with age.

If resident is over 70 years of age then the physician and clinical leadership should discuss sending the resident to the hospital if respiratory symptoms worsen.

Any resident that has symptoms of respiratory distress that may indicate respiratory arrest is pending must be sent out to the hospital.

Recovery on the Contamination /Observation Unit

Staff should:

1. Have the physician evaluate residents recovery and status
2. Encourage activity as tolerated.
3. Provide emotional support to the resident and family
4. Monitor vital signs, weight, appetite, and psychosocial status of the resident for the duration of their time spent on the unit.
5. Have therapy screen for any needs. As a positive COVID-19 resident, they will be considered Medicare A, skilled level of care, if eligible.
6. Have an open line of communication with the resident, family or POA throughout the recovery process.
7. Schedule a phone care plan conference, if possible.



Discharging from the Contamination/Observation Unit

(Per CDC -Discontinuation of Transmission-Based Precautions 7/17/20 update)

COVID-19 positive residents that have manageable symptoms will remain on the observation/contamination unit until:

1. Patients with mild to moderate illness who **are not severely immunocompromised:**
 - 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
2. Patients who are **not severely immunocompromised** and who were **asymptomatic** throughout their infection will remain on the observation/contamination unit until:
 - A. 10 days have passed since the date of their first positive viral diagnostic test.
3. Patients with severe to critical illness or who **are severely immunocompromised:**
 - A. At least 20 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
4. Residents who are **severely immunocompromised** and were asymptomatic throughout their infection will remain on the observation/contamination unit until:
 - A. 20 days have passed since the date of their first positive viral diagnostic test.

Please Note: Except for rare situations, a test-based strategy is no longer recommended to determine when to discharge a resident from the observation/contamination unit.

In some instances, a test-based strategy could be considered for discontinuing Transmission-based Precautions earlier than if the symptom-based strategy were used. However, many individuals will have prolonged viral shedding, limiting the utility of this approach. A test-based strategy could also be considered for some patients (e.g., those who are severely immunocompromised¹) in consultation with local infectious diseases experts if concerns exist for the patient being infectious for more than 20 days.

The criteria for the test-based strategy are:

1. Patients who are symptomatic:
 - A. Resolution of fever without the use of fever-reducing medications and
 - B. Symptoms (e.g., cough, shortness of breath) have improved, and
 - C. Results are negative from at least two consecutive respiratory specimens collected ≥ 24 hours apart (total of two negative specimens) tested using an FDA-authorized molecular viral assay to detect SARS-CoV-2 RNA. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for 2019 Novel Coronavirus (2019-nCoV).
2. Patients who are not symptomatic:
 - A. Results are negative from at least two consecutive respiratory specimens collected ≥ 24 hours apart (total of two negative specimens) tested using an FDA-authorized molecular viral assay to detect SARS-CoV-2 RNA. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for 2019 Novel Coronavirus (2019-nCoV).



Media Statement

At **[FACILITY NAME]**, making sure that our patients and residents are cared for in a safe and healthy environment is our top priority.

From the onset of current COVID-19 crisis, we have been both diligent and proactive in our efforts to reduce the potential for an active COVID-19 case(s) within our center.

Additionally, we have prepared for the scenario in which an active case is identified at our facility. This includes, among other things, establishing a designated observation unit for suspected or confirmed COVID-19 cases.

We currently have **[NUMBER]** confirmed positive COVID-19 cases at our center, and we are doing everything we can to stop the spread of the virus within our facility. We are in very close communication with local and state health officials, and our staff and residents are following the recommended preventative actions.

We have restricted visitors from entering our facility and cancelled all group activities, and we are closely monitoring the health of each patient/resident. We will continue to take all appropriate measures until the virus has been eradicated from our center.

We understand that family members are concerned about the spread of COVID-19 (coronavirus) and how it may impact their loved one at a nursing center. We have and will continue to take every precaution to ensure the health and well-being of those entrusted to our care, as well as the health and safety of our teammates.



Media Talking Points

- ❖ Due to patient privacy laws, we are unable to share any further specific information about the confirmed case(s) in our facility, but we have notified their immediate family members/guardian.
- ❖ Resident safety is a top priority for **[FACILITY NAME]**. This virus is especially dangerous to our population—older adults with underlying health conditions—so, this is a critical issue that requires our immediate attention.
- ❖ **[FACILITY NAME]** is in close contact with our local and state health departments, as well as the CDC, to stay up to date on the information to prevent and manage the spread of Coronavirus.
- ❖ Skilled nursing and assisted living providers rely on local, state and federal resources to help prevent the spread of this virus.
- ❖ We have reviewed and updated our infection prevention and control plans and our emergency communication plan.
- ❖ We are following general public health best practices: hand washing, using alcohol-based hand sanitizers and covering coughs.
- ❖ We have reinforced to our staff that anyone who is sick should stay home, and we are screening all essential personnel as they enter the building.
- ❖ We will continue to keep family members up to date as this situation unfolds, so they have the latest information about their loved ones.
- ❖ We are currently restricting all non-essential personnel, per direction from local health department (as well as the federal/state government).
- ❖ Family members can interact with their loved ones by using video chat, calling, texting or checking in on social media. Tablets have been purchased help facilitate communication between our residents and their loved ones.
- ❖ **Facility may receive different recommendations based on each locality**



Common Media Questions

Should families who are worried move their loved ones out of skilled nursing centers or assisted living communities?

- ❖ No. Moving the elderly or frail is risky and often has long-lasting impacts. Research around natural disasters and other emergency events has proven this over time. CDC does not currently recommend transferring residents either home or to the hospital.

How concerned are you for skilled nursing center or assisted living residents?

- ❖ We know that the frail and elderly are especially susceptible to this virus. That's why we are in close communication with our local health department, CDC and CMS to ensure we have the latest information and resources available.

Are you having trouble getting things like masks and gowns?

- ❖ We have heard that some long-term care providers are having some of the same difficulties as other health care providers getting masks and gowns. In our facility, we have been fortunate to have ample supply of PPE and tests **[PROVIDE INFO ON YOUR SUPPLIES (e.g., conservation efforts)]**.
- ❖ In the event that we are in need of equipment or supplies we will be reaching out to the state and local health departments and area hospitals/other health care providers to provide assistance.
- ❖ It's important to remind the public that the CDC does not recommend surgical masks for the general public—cloth face coverings are acceptable—so we can prioritize masks for health care workers. We also urge members of the public to not hoard items like hand sanitizer, so we can make that available to residents and staff, who need to use it regularly.

If staff have to stay home because they are sick/schools close, how are you ensuring that there are enough staff to care for your residents?

- ❖ Our state and national associations are encouraging both federal and state governments to waive current licensing requirements that would hinder care professionals from working across state lines, so we can potentially address any shortages due to employees needing to stay home.
- ❖ Our state and national associations are also advocating for priority testing for our employees and residents, so we can quickly identify whether staff need to remain at home or if they can come back to work.
- ❖ Our center is actively recruiting both permanent, as well as temporary employees to help ensure we have adequate staffing. In addition to hiring direct care staff, we are adding hospitality aides to do such tasks as delivering meals, filling water pitchers, making beds, assisting with activities, and helping connect patients/residents with loved ones and family members via phone, tablets. Many individuals across the community have been laid off from their employer due to the COVID-19 crisis, including healthcare workers. We are working hard to recruit additional team members to help be able to provide relief for our caregivers.



Resource Information

- ❖ To decrease the risk of viral outbreaks in long term care centers, two processes need to be in place.
 - First, efforts should focus on how to decrease the introduction of viruses into a facility.
 - Second, steps to decrease the spread of a virus between residents need to be in place and followed consistently.
 - Even then, outbreaks may still occur. Facilities should have a process to limit the spread of a virus and also treat individuals with an infection to decrease the risk of illness exacerbation, hospitalization, and in severe cases, death.

- ❖ Steps to help prevent the introduction of a virus into long term care centers (or any health care facility) include:
 - Keeping all individuals from visiting the facility, including family, volunteers and employees.
 - Requiring individuals visiting a facility to wear a mask when viral infections are at increased levels in the community.
 - Not applicable if visitors are not being permitted.
 - Encouraging frequent hand hygiene by making alcohol-based hand sanitizer dispensers readily available, in locations such as in or near each resident's room as well as in the entry area and common areas.
 - Immunization of health care workers (e.g. influenza, measles, diphtheria, pertussis, chicken pox) or limiting health care workers physical interaction with residents when not immunized or using masks when such viral infections are found at increased levels in the community.

- ❖ Steps to help decrease the risk of viral spread within a facility include:
 - Ongoing hand hygiene at high levels. This can be achieved with: Readily available alcohol-based hand sanitizers in locations such as in or near each resident's room, common areas, etc.
 - Regular and frequent internal monitoring systems of hand hygiene with regular feedback to staff.
 - Visual reminders that hand hygiene helps residents stay healthy.
 - Early identification of viral infections that cause upper respiratory illness (e.g. "colds", "flu", or "winter crud") that lead to steps that prevent viral spread. Preventative measures include: Early contact isolation and droplet protection for individuals with flu-like symptoms before a definitive diagnosis is made. This includes: Keeping ill individuals away from healthy individuals (e.g. ideally by cohorting ill residents together, though cohorting may not be possible given the physical space and structure of facilities).
 - Use of masks on residents with symptoms if they need to leave their rooms, which should be severely restricted.
 - Use of personal protective equipment by staff and visitors for droplet protection.
 - Use of appropriate cleaning products on surfaces that are cytotoxic for common viral infections and changing these cleaning products when the harder to kill infectious agents are identified and requires special cleaning products, such as C. diff, norovirus and adenovirus, which should be readily available to the facility staff.

- ❖ CMS issued infection control regulations in November 2016. These regulations were designed to help decrease the risk of infectious outbreaks in nursing centers and require each nursing center to have an infection control plan that must describe:
 - An infection prevention and control program. The facility must establish an infection *prevention and* control program that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist;
 - A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;
 - When and to whom possible incidents of communicable disease or infections should be reported;
 - Standard and transmission-based precautions to be followed to prevent spread of infections;
 - When and how isolation should be used for a resident; including but not limited to: The type and duration of the isolation, depending upon the infectious agent or organism involved, and;
 - A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.
 - The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and
 - The hand hygiene procedures to be followed by staff involved in direct resident contact.

- ❖ The CMS regulations also require each nursing center to designate at least one employee to serve as an Infection Preventionist, who is both a clinician (e.g. nurse) and has received additional training and certification in infection control.
 - There are three training programs available including one designed by AHCA/NCAL. They all require approximately 20 to 25 hours of training.

- ❖ AHCA/NCAL has recommended several steps to help decrease the risk of future viral outbreaks in nursing centers:
 - AHCA/NCAL has offered to provide our certificate course for free to those centers who provide care to high risk individuals (e.g. pediatrics, ventilators, HIV, transplants, and ESRD).
 - State health departments should ensure each nursing center has alcohol-based hand sanitizers that are readily available to each room and at entry to the facility as well as in common areas for staff and visitors.
 - State health departments should ensure all health care workers receive the influenza vaccine. If a worker chooses to decline the vaccine, during periods of time when there is an increase in influenza virus in the community, that individual should be required to wear a mask. If they are unable to wear a mask, they should not provide direct patient care. Several states and hospitals have adopted this type of approaches.
 - State health departments should assure health care facilities use appropriate cleaning supplies that are cytotoxic to common viruses and pathogens (per CDC and EPA labeling for claims against common viruses and pathogens). All health care facilities should have a supply of additional cleaning agents for hard to kill pathogens when such pathogens are identified or suspected (e.g. C. diff, adenovirus, norovirus).

Utilizing Non-Direct Care Staff to Support Needs

COVID-19 has interrupted usual daily operations in all long term care facilities. This means some direct or non-direct care staff usual duties are on hold or not urgent during this pandemic. Thus, there is opportunity to engage those staff in supporting activities that must continue despite the pandemic disruptions. Below are some ideas to consider.

Typical Nurse Aide Duties to be Stopped/Shifted to Other Non-Direct Care Staff:

- ❖ Deliver water and snacks
- ❖ Deliver linen and supplies
- ❖ Restocking supplies
- ❖ Assisting residents in wheelchairs to/from events (bathing, etc.)
- ❖ Take menu/orders from residents
- ❖ 1-on-1 with resident who have behavioral challenges or need socialization
- ❖ Deliver meals to residents during mealtime
- ❖ Applying/removing glasses and hearing aids to residents
- ❖ Bed making
- ❖ Responding to call lights
- ❖ Assisting with feeding non-choking or non-aspiration risk residents
- ❖ Doing errands for the resident
- ❖ Doing personal care such as combing hair or washing faces/hands
- ❖ Stay with resident while in the bathroom to free up NA to do other tasks while waiting to transfer

Nurse and Nurse Aide duties that could be supported by PT, OT and SLP staff:

- ❖ Restorative and functional ADL and mobility maintenance services
- ❖ Perform and document routine vital signs, orthostatic BPs, etc.
- ❖ Assisting to feed moderate risk residents (history of some choking issues)
- ❖ Any other basic support duties that could also be performed by non-direct care staff

Typical Nurse (or some medication aide) duties to be shifted, stopped, or requests to reduce/discontinue:

- ❖ Request discontinue of non-critical medications (e.g. vitamins, calcium)
- ❖ Request discontinue or reduced blood sugar checks (e.g. decrease to daily or weekly)
- ❖ Request discharge of sliding scale insulin and standard/set amount of long-acting insulin administered every day
- ❖ Request to reduce dressing changes to daily or biweekly (as appropriate)
- ❖ Routine vital signs decrease to weekly or monthly (as appropriate)
- ❖ Orthostatic B/Ps - reduce to one time daily or weekly (as appropriate)
- ❖ Stop routine monthly vital signs

Miscellaneous

Advanced Directives

When the first case of COVID-19 is confirmed in the facility, advanced directives must be reapproached.

The Social Service Director or designee should systematically have a conversation with each resident or their representative. This can be a difficult conversation, but considering the fact that we provide care to residents with multiple co-morbidities, it is necessary.

Families and representatives should know their loved one survival rate is not very likely if they have pre-existing conditions, like a respiratory illness, prior to testing positive for COVID-19.

Families and representatives should understand that sending their loved one to the hospital is not necessarily safer as they could be exposed at the hospital. As a Shelter-in-Place we should do all we can to keep residents in the facility unless it is absolutely necessary.

Unfortunately with Covid19 we are faced with the fact that we may need to approach end of life discussions at this time. The discussion will have to be compassionate but clear and honest regarding end of life in regards to COVID-19.

Choices should include:

- ❖ Discussion on Advanced directive decisions
- ❖ Choices with Palliative care vs Hospice
- ❖ Hospital transports and defining need or preference

Any changes to advanced directives should be communicated with the staff once changes have been documented. Care plans and the residents Kardex must be updated to reflect desired wishes.

Cleaning of COVID-19 Rooms

- ❖ Refer to Healthcare Services manual for policy and procedures on cleaning COVID-19 rooms

Hospice Services

- ❖ Limit to 1 nurse per week
- ❖ Aides are not permitted
- ❖ Family is only permitted to visit if the resident is actively dying

MISCELLANEOUS INFO & GUIDANCE

COVID-19 IgG/IgM Rapid Test Cassette

Reference Product: 100598 (Emergency Use Only)

Intended Use

COVID-19 IgG/IgM Rapid Test Cassette (Serum) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human serum. This test provides only a presumptive test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

Summary and Explanation of the Test

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.⁴ The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 2-3 weeks after exposure. IgG remains positive, but the antibody level drops overtime. The COVID IgG/IgM test is an immunological diagnostic test based on the immunochromatographic lateral flow principle.

Biological Principles

The COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow immunochromatographic assay for professional use only. The test uses anti-human IgM antibody (test line IgM), anti-human IgG (test line IgG) and goat anti-rabbit IgG (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates) and rabbit IgG-gold conjugates.

1. The sample (whole blood, serum, plasma) is applied to the sample well.
2. The sample buffer (Negative Control), a buffered diluent containing 0.094% sodium azide as a preservative. The reagent is supplied in a plastic dropper vial. Use as supplied.
3. When the specimen (whole blood, serum, plasma) followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. If present, a distinct burgundy line or lines will appear.
4. There is an internal procedural control with the test to ensure that the proper volume of sample was aliquoted and membrane wicking has occurred. This is indicative of a colored line that will change from blue to red in the control line region.

Reagents and Materials Provided

The maximum number of tests obtained from this test kit is listed on the outer box.

1. COVID-19 IgG/IgM Test Devices, containing immobilized polyclonal anti-COVID-19 IgG and anti-COVID-19 IgM. The devices are packaged in individual foil pouches with desiccants. Store at 2-30 C when not in use.
2. Sample Diluent (Negative Control), a buffered diluent containing 0.094% sodium azide as a preservative. The reagent is supplied in a plastic dropper vial. Use as supplied. Store at 2-30 C when not in use.
3. 25 µL/ 125µL disposable plastic transfer pipettes

Materials Not Provided

1. Specimen or blood collection containers: sodium or lithium heparin tubes
2. Vortex
3. Interval timer
4. Autoclave
5. Disposable latex gloves

PRECAUTIONS

1. For emergency and professional use only.
2. Package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

SHELF LIFE AND STORAGE

COVID-19 IgG/IgM test is stable until the expiration date printed on the box when stored at 2 to 30 C. The Test Device should be used within 5 minutes after removal from the sealed foil pouch.

PROCEDURE NOTES

Diagrams of the COVID-19 IgG/IgM Test Device supplied with the kit are shown below.

SPECIMEN COLLECTION – COVID-19 IgG/IgM Rapid Test Cassette can be performed using either whole blood, serum, plasma.

Whole Blood

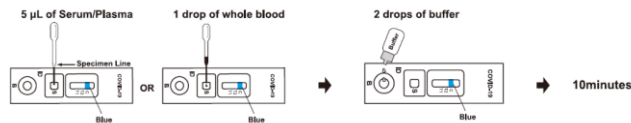
1. Whole blood collected in the amount of (10µL) via lancet or fingerstick can be used.
2. Sample must be tested immediately.

Serum/Plasma

1. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
2. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum specimens may be stored at 2-8°C for up to 3 days.
3. Bring specimens to room temperature prior to testing.

TEST PROCEDURE

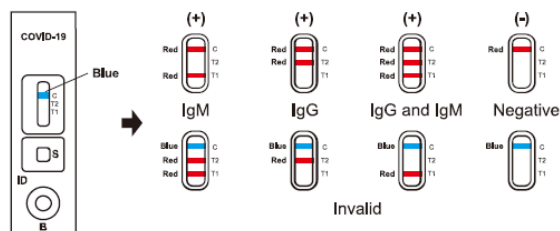
1. Bring all Test Devices, reagents and samples to room temperature (20-25 C) before testing.
2. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within ten minutes.
3. Place the test device on a clean and level surface.
4. With a 5 µL mini plastic dropper provided, draw serum specimen to exceed the specimen line as showed in the following image and then transfer drawn serum specimen into the sample well (S).
5. Then immediately add 2 drops (about 80µL) of sample buffer to the buffer well (B), take care to avoid air bubbles.
6. Read the results within 10 minutes of incubation.



External Control

1. A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
2. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Interpretation of Results



1. **NEGATIVE:** The colored line in the control line region (C) changes from blue to red. No line appears in the test line regions T1 or T2. The result is negative.
2. **IgM POSITIVE:** The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region T1. The result is anti-COVID-19 IgM positive.
3. **IgG POSITIVE:** The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region T2. The result is anti-COVID-19 IgG positive.
4. **IgG and IgM POSITIVE:** The colored line in the control line region (C) changes from blue to red, and two-colored lines appear in test line regions T1 and T2. The result is anti-COVID-19 IgM and IgG positive.

INVALID Test Result:

1. Control line is still completely or partially blue. The test is invalid since the Presence of a blue control band indicates the test procedure was performed improperly or that deterioration of reagents has occurred.
2. If any result is difficult to interpret, the test should be repeated with the same sample to eliminate the potential for error. Obtain a new sample and retest when the original sample repeatedly produces unreadable results.
3. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact Aytu BioScience at 720-437-6580.

QUALITY CONTROL

1. At the time of each use, kit components should be visually examined for obvious signs of microbial contamination, freezing, or leakage. Do not use contaminated or suspect reagents.
2. Internal controls: Internal controls are contained within the test strip and therefore are evaluated with each test.
3. A Red band appearing at the Control line serves as a procedural control and indicates the test has been performed correctly, that proper flow occurred and that the test reagents were active at the time of use.
4. A clean background around the Control or Test lines also serves as a procedural control. Control or test lines that are obscured by heavy background color may invalidate the test and may be an indication of reagent deterioration, use of an inappropriate sample or improper test performance.

Testing for COVID-19 in Long Term Care

Testing continues to be a significant point of concern for LTC providers. Providers are either reporting long lags in turnaround times for tests (7-10 days), or lack of access to testing at all. There are several key issues in obtaining reliable access to testing, including:

- **CDC Guidance:** LTC residents fall into priority category two for testing, according to [CDC guidance](#). While not required, some state and local health departments and/or individual clinicians may use this guidance to prioritize testing.
- **State prioritization:** State and local health departments are often directing priority for testing, so your access to testing is likely be dependent on policies at the state level.
- **Backlog of tests among commercial labs:** Many commercial labs are overwhelmed and that is leading to a backlog of tests and longer turnaround times for results.
- **Shortage of supplies:** We are also hearing that labs themselves are facing a shortage of testing supplies, such as nasal swabs, which may be adding to existing delays and/or limiting tests to help conserve supplies.

There has been a great deal of press around new rapid Point-of-Care (POC) COVID-19 tests, such as the Abbott ID NOW COVID-19 test. At this point, it does not appear that they are widely available for purchase/distribution. In addition, most [emergency use authorization](#) (EUA)-authorized tests for COVID-19 are authorized for use by laboratories that meet the Clinical Laboratory Improvement Amendments (CLIA) waiver for either moderate or high complexity testing. It is unclear whether these new POC tests can be performed in a setting without this waiver. New information is being released daily and AHCA/NCAL will continue to investigate whether these tests can be performed in and made available to the LTC setting.

There has also been a lot of activity around antibody blood tests. Several companies have already received an EUA from the FDA for their antibody tests, while some are still pending approval. It's important to understand that antibody tests are NOT the same as a Polymerase Chain Reaction (PCR) test. The PCR test is looking for genetic material from the virus, while an antibody test is looking to see if a person has antibodies from COVID-19 present in their system. Antibodies generally develop about 5-14 days after contracting the infection and can remain for months after an infection. If a person has these antibodies, they can offer short-term (weeks to months) protection against contracting COVID-19. Whether these antibodies provide long-term protection is not yet known. The antibody test, unlike the PCR test, cannot tell you if someone is currently infected and sick with COVID-19. Antibodies start to become positive for some people when they still have virus in the body, but antibodies will stay positive after virus is gone. A complete comparison of the two tests is shown on the next page.

AHCA/NCAL continues to press on this issue including developing a list of credible [vendors](#) that can provide COVID-19 testing with reasonable turnaround times.

AHCA/NCAL also strongly recommends that providers, regardless of testing, **assume that COVID-19 it is already in their surrounding community and may be in their facility**. AHCA/NCAL has developed a resource on what to do when COVID-19 enters your building [here](#). Linked in this document is also a guide on [cohorting](#) residents within your building, which CMS also recommends in [guidance](#) released on April 2.

COVID-19 PCR vs Antibody Testing

Jessica Cataldi MD, MSCS. 04.03.20

	PCR	Antibody (IgM/IgG)
What it measures?	Genetic material from the virus, usually measured from respiratory secretions on a nasopharyngeal swab	Antibodies (immune proteins) made by the body to help recognize the virus, almost always measured from the blood
When is it positive?	When the virus or genetic material from the virus is in the body	After the body has been infected with the virus and had time to make antibodies. IgM usually positive by about 5 days after symptoms have started, IgG may take longer to become positive (the body starts making IgM first). We do not know how long COVID-19-related antibodies will stay positive in the blood. For some infections, IgG can last for years and for others it may start to go away after months.
When could you get a 'false positive'?	False positives are very rare because you are looking for specific genetic material from the virus. COVID-19 tests do not cross-react (turn positive) in the presence of other coronaviruses.	COVID-19 antibody tests may be positive if a person's body has made antibodies to some other virus or protein in the past and if those antibodies are very similar to the COVID-19 antibodies. The Specificity of test can give you an estimate of how often you might see false positives. If Specificity is 100%, then 100% of positive results mean you have COVID-19 antibodies. If Specificity is 90%, then 90% of positive results mean you have COVID-19 antibodies, and 10% of positive results mean something else (ie 10% are 'false positives').
When could you get a 'false negative'?	False negatives can happen if there is too little virus in the sample to be detected. This can happen if you don't get a good sample from the patient (not enough secretions on the swab, not swabbed deep enough into the nose) or if the sample degrades over time (long transport to the lab). Immediately after a person is exposed to someone else with COVID-19, they may have only a small amount of virus in their body. The amount of virus increases initially and is highest in the first few days of symptoms, then the amount of virus in the body decreases around day 5-7. Someone may still be sick and having symptoms even when the amount of virus in their body is decreasing. If you send PCR test on someone very early before symptoms or later after 5-7 days of symptoms, their test may be negative because there is not enough virus in their body to detect.	It takes the body time to make antibodies, so you may get a negative tests if you test someone too early in the course of their infection. IgM antibodies start to show up in some people after about 5 days of symptoms and are present in almost all people who have had COVID-19 disease by 14 days after their start of symptoms. IgG antibodies take longer to show up and are seen in some people who have had COVID-19 disease by 14 days and almost all people by 1 month. Testing antibodies cannot tell you if someone is currently infected. Testing for antibodies tells you if someone has been exposed to or infected with something before and has made antibodies in response.
What is it helpful and not helpful for?	PCR tells you if someone is currently infected and sick with COVID-19 and if they have virus in their body still. It may be helpful for determining whether someone is contagious, so long as you are able to get a good specimen for testing. PCR cannot tell you if someone had COVID-19 last week or last month. Even in someone who is still sick, their PCR may become negative after about a week of illness as the amount of virus in the body decreases even before they start to feel better.	Testing antibodies can tell you if someone has had COVID-19 before, and antibodies will be positive even in some people who have been exposed and not gotten sick. We don't know if having antibodies offers long term protection against getting COVID-19 again, but they probably offer at least short-term (weeks to months) protection. Testing antibodies cannot tell you if someone is currently infected and sick with COVID-19. Antibodies start to become positive for some people when they still have virus in the body, but antibodies will stay positive after virus is gone.

PERFORMANCE CHARACTERISTICS

Clinical Performance

The COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) has been evaluated with the 113 samples obtained from patients exhibiting pneumonia or respiratory symptoms. The results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs etc.) of "Diagnosis and treatment of novel coronavirus pneumonia".

Regarding the IgM test, the test result comparison to RT-PCR.

Method	RT-PCR		Total	
	Positive	Negative		
COVID-19 IgG/IgM Test	Positive	87	0	87
	Negative	12	14	26
		99	14	113

Regarding the IgG test, we have counted the positive rate of the 36 of 113 patients during the convalescence period.

Method	Number of Patients during the convalescence period	Total	
COVID-19 IgG / IGM Test	Positive	35	35
	Negative	1	1
Total	36	36	

The sensitivity of IgM test is 87.9% (87/99) and specificity is 100% (14/14) comparison to RT-PCR. The sensitivity of IgG test is 97.2% (35/36) during the convalescence period, and specificity is 100% (14/14).

LIMITATIONS

1. Use fresh samples only.
2. This test has not been reviewed by the FDA.
3. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
4. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
5. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
6. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

References

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81: 85-164.
2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.

For ordering, Customer Inquiries and Technical Support Contact:











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Glossary of Symbols

 Manufacturing Date	 Read Usage Instruction
 Store between 2-30C	 Catalogue Number
 Lot Number	 Biological Sample
 Re-use not Allowed	 Caution, Consult Document
 Test per kit	 Use by



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VIEWPOINT

The Importance of Addressing Advance Care Planning and Decisions About Do-Not-Resuscitate Orders During Novel Coronavirus 2019 (COVID-19)

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The novel coronavirus disease 2019 (COVID-19) pandemic is challenging health care systems worldwide and raising important ethical issues, especially regarding the potential need for rationing health care in the context of scarce resources and crisis capacity. Even if capacity to provide care is sufficient, one priority should be addressing goals of care in the setting of acute life-threatening illness, especially for patients with chronic, life-limiting disease.

Clinicians should ensure patients receive the care they want, aligning the care that is delivered with patients' values and goals. The importance of goal-concordant care is not new or even substantially different in the context of this pandemic, but the importance of providing goal-concordant care is now heightened in several ways. Patients most likely to develop severe illness will be older and have greater burden of chronic illness—exactly those who may wish to forgo prolonged life support and who may find their quality of life unacceptable after prolonged life support.¹ In addition, recent reports suggest that survival may be substantially lower when acute respiratory distress syndrome is associated with COVID-19 vs when it is associated with other etiologies.^{2,3}

In this context, advance care planning prior to serious acute illness and discussions about goals of care at the onset of serious acute illness should be a high priority for 3 reasons. First, clinicians should always strive to avoid intensive life-sustaining treatments when unwanted by patients. Second, avoiding nonbeneficial or unwanted high-intensity care becomes especially important in times of stress on health care capacity. Third, provision of nonbeneficial or unwanted high-intensity care may put other patients, family members, and health care workers at higher risk of transmission of severe acute respiratory syndrome coronavirus 2. Now is the time to implement advance care planning to ensure patients do not receive care they would not want if they become too severely ill to make their own decisions. As eloquently pointed out by an intensivist, "If you do not talk with [your family] about this now, you may have to have a much more difficult conversation with me later."⁴ Several online resources can guide these advance care planning discussions.⁵⁻⁷

For patients in a community setting or living in a nursing home, clinicians should engage in discussions about goals of care now, especially with older patients with chronic disease. During this pandemic when non-essential medical visits are currently limited, these conversations may need to occur via telemedicine (either as a stand-alone appointment or in combination with

an appointment designated or scheduled for another purpose). This process should include primary care and specialty clinicians (eg, cardiologists, pulmonologists, nephrologists, oncologists, and geriatricians), and patients might appreciate this opportunity to discuss advance care planning. Depending on state regulations, patients with chronic life-limiting illness should be offered the option to complete a physician order for life-sustaining treatments form, especially if they would not want to receive cardiopulmonary resuscitation (CPR) or mechanical ventilation.

For hospitalized patients, one focal point for goal-concordant care is related to discussions of code status or the use of CPR and advanced cardiac life support (ACLS). Many hospital-based clinicians over-emphasize code status as the first step of a goals-of-care discussion, but asking patients about CPR before assessing values and goals leads to ineffective code status discussions. During this pandemic, it is equally important to understand a patient's values and goals prior to discussing code status; however, the importance of avoiding inappropriate CPR has increased for 2 reasons. One reason is that although unwanted or nonbeneficial CPR under any circumstance may risk increasing psychological distress for patients' family members,⁸ inappropriate CPR during the pandemic is especially stressful and potentially dangerous for health care workers. Another reason is that nonbeneficial or unwanted ACLS will strain available resources for personal protective equipment because multiple health care workers are needed for effective ACLS. Therefore, the COVID-19 pandemic heightens the importance of implementing do-not-resuscitate (DNR) orders for appropriate hospitalized patients.

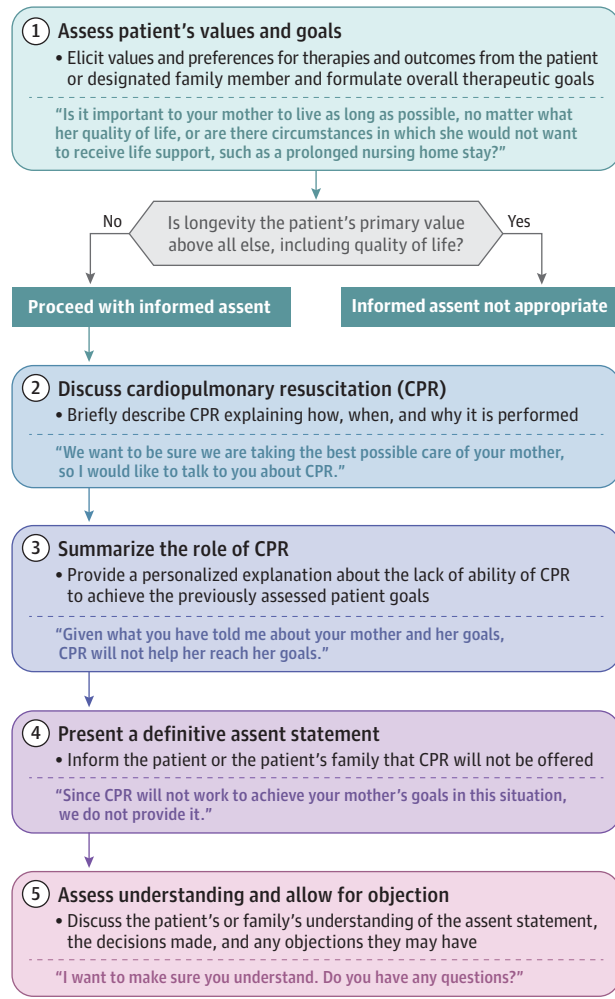
The implementation of DNR orders can occur in 3 situations. First, patients or their surrogate decision makers may clearly understand and communicate that the patient would not want CPR if the heart were to stop and may even have a physician's order for life-sustaining treatments form that specifies such. Second, patients or their surrogate decision makers may follow the recommendation of a clinician to forgo CPR; this may occur through informed consent or, occasionally, informed assent (as discussed below).⁹ Third, in extreme situations in which CPR cannot possibly be effective, clinicians in some health care settings may unilaterally decide to write a DNR order.¹⁰ This latter approach is not uniformly accepted and, prior to COVID-19, it rarely had a role. During this pandemic, however, in extreme situations such as a patient with severe underlying chronic illness and

acute cardiopulmonary failure who is getting worse despite maximal therapy, there may be a role for a unilateral DNR to reduce the risk of medically futile CPR to patients, families, and health care workers.¹⁰

Informed assent may be a more acceptable approach to code status discussions than medical futility and may be useful for patients in whom CPR is exceedingly unlikely to allow a successful return to a quality of life they would find acceptable.⁹ The **Figure** provides a proposed guide for an approach to having an informed assent discussion with a patient or family member of a patient for whom the clinician believes CPR is not indicated. The advantage of informed assent over a more traditional informed consent approach is that the clinician does not ask the patient or designated family member to take responsibility for the decision but rather asks the patient or family member to allow the clinician to assume responsibility. Some family members may be willing to permit clinicians to make this decision while simultaneously being unable to accept responsibility themselves, even if they agree, because of the psychological burden it places on them. In this setting, informed assent may provide family members a way to agree with the clinician's determination without assuming responsibility. Importantly, this approach places great responsibility on clinicians to enact careful prognostication and thoughtful, respectful, open communication with family members. This same responsibility is also present for informed consent.

The COVID-19 pandemic is placing tremendous stress on health care systems. There are many important components of an appropriate response to this pandemic, including public health measures to reduce rapidity and extent of spread. Another important element of the best possible response is to ensure that clinicians have high-quality discussions both about advance care planning for individuals in the community, especially those of older age and with chronic illness, and about goals of care with patients or their families when patients have illness that requires hospitalization.

Figure. Proposed Components of Informed Assent Framework



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REFERENCES

1. Fried TR, Bradley EH, Towle VR, Allore H. Understanding the treatment preferences of

seriously ill patients. *N Engl J Med*. 2002;346(14):1061-1066. doi:10.1056/NEJMsa012528

2. Wu C, Chen X, Cai Y, et al Risk factors associated with acute respiratory distress syndrome and death in patients with coronavirus disease 2019 pneumonia in Wuhan, China. *JAMA Intern Med*. 2020; doi:10.1001/jamainternmed.2020.0994

3. Arentz M, Yim E, Klaff L, et al. Characteristics and outcomes of 21 critically ill patients with COVID-19 in Washington State. *JAMA*. 2020. doi:10.1001/jama.2020.4326

4. Rubenfeld G. The coronavirus is a chance to have the end-of-life conversations we need. *The Globe and Mail*. March 16, 2020. Accessed March 3, 2020. <https://www.theglobeandmail.com/opinion/article-the-coronavirus-is-a-chance-to-have-the-end-of-life-conversations-we/>.

5. Sudore RL, Schillinger D, Katen MT, et al. Engaging diverse English- and Spanish-speaking older adults in advance care planning: the PREPARE randomized clinical trial. *JAMA Intern Med*. 2018;178(12):1616-1625. doi:10.1001/jamainternmed.2018.4657

6. Goodman E. The Conversation Project is dedicated to helping people talk about their wishes

for end-of-life care. Institute for Healthcare Improvement. Published 2020. Accessed March 21, 2020. <http://theconversationproject.org>.

7. Back AL, Arnold RM, Edwards K, Tulskey JA. COVID-ready communication skills. VITALtalk. Published 2020. Accessed March 21, 2020. <https://www.vitaltalk.org/guides/covid-19-communication-skills/>.

8. Ornstein KA, Aldridge MD, Garrido MM, et al The use of life-sustaining procedures in the last month of life is associated with more depressive symptoms in surviving spouses. *J Pain Symptom Manage*. 2017;53(2):178-187 e171. doi:10.1016/j.jpainsymman.2016.08.023

9. Curtis JR, Burt RA. Point: the ethics of unilateral "do not resuscitate" orders: the role of "informed assent". *Chest*. 2007;132(3):748-751. doi:10.1378/chest.07-0745

10. Bosslet GT, Kesecioglu J, White DB. How should clinicians respond to requests for potentially inappropriate treatment? *Intensive Care Med*. 2016; 42(3):422-425. doi:10.1007/s00134-015-4192-4

Guidance on the Role of Hospice Services in LTC Facilities During COVID-19 Pandemic

Long-term care facility residents and staff are experiencing a number of stressors and losses. LTC facility staff are experiencing challenges both personally and professionally. This has increased the need for hospice's holistic, end-of-life care for patients and families as well as grief and bereavement support for residents, families and staff. It is critical that LTC and hospice staff partner together to ensure simple, clear and supportive communication, minimizing mixed messages.

To prevent the spread, facilities and health care workers need to significantly reduce the number of people entering and interacting with residents and staff. This needs to be balanced with providing the most benefit to the resident and family, especially at the end-of-life. The risk-benefit must be made on a case-by-case basis, incorporating the best interest of the resident, against the risk of introducing the virus to other residents, a cohort that has a very high morbidity and mortality rate. According to the [CDC Morbidity and Mortality Weekly Report](#), the current mortality rate ranges from 10-27% for elderly over the age of 85. This decision process will need to be adjusted as the COVID-19 situation evolves in each local community and building.

Some Broad Principles to Consider

1. Use alternate methods to conduct the visit (phone call, phone with video, or other device with audio and video capability), particularly for routine visits.
2. Minimize the number of different hospice staff dedicated to a SNF.
 - a. Consider assigning staff to facilities and minimizing entry into multiple buildings as movement of staff between buildings is suspected to be one mechanism of COVID-19 spread.
 - b. If COVID-19 is discovered in a building, hospice staff should strongly consider limiting their movement to other buildings and self-monitor for fever or respiratory symptoms.
3. Bundle visits to minimize the number of different days hospice needs to be in the building.
4. Maximize the number and types of care and services provided by a single staff member (hospice or LTC) to minimize different people needing to enter a room, particularly at COVID spreads.

Assessing Resident Status

Assess current status to determine stability of patients.

1. Is pain/symptom management under control?
2. Are there active signs and symptoms of approaching death?
3. Are there complex family dynamics or psychosocial issues?

Questions to ask prior to arranging a visit:

- a. Who needs to provide this service (hospice or facility staff)?
- b. Can it be accomplished by phone call, phone with video, or other device with audio and video capability? Can the facility staff help the patient connect?

Caring for Stable Patients

1. Use alternative methods of completing routine updates, assessments, interventions such as telehealth technology. Reserve in-person visits for patients whose condition warrants and can't be accomplished by other mechanisms.
2. Review the care plan with patient as appropriate, family and staff and consider modifying the current plan to minimize number of in-person contacts and include phone or telehealth visits in the care plan.
3. Bundle visits on different days to a single day.
4. Ensure frequent and consistent communication with family to provide updates and answer any questions.

Questions to ask prior to arranging a visit:

- a. Who needs to provide this service (hospice or facility staff)?
- b. Can it be accomplished by phone call, phone with video, or other device with audio and video capability?
- c. Are there other hospice staff already conducting a visit?

Patients Approaching Death¹

1. In these situations, implement [CMS guidance for hospice providers](#) and work to allow visitation by family, again trying to minimize entry.
2. Consider adjusting the care plan to minimize number of different staff entering building.
3. Hospice nurse could consider providing both hospice support and care but also ADLs or other nursing care during a visit to help minimize interactions with staff.
4. Consider engaging hospice for added psychosocial and spiritual support, expertise and resources for residents not enrolled in hospice but who are approaching end-of-life. There may also be an opportunity for hospice admission for those who are actively dying of COVID. This may free up staff to provide care to other residents in the facility.
5. Most people are afraid of dying alone and hospice staff can help.

¹ Assess for signs of approaching death and determine whether “pre-active phase of dying” or “active phase of dying”. The pre-active phase of dying could last a couple of weeks versus the active phase of dying could last about 3 days.

Questions to ask prior to arranging a visit:

- a. Who needs to provide this service (hospice or facility staff) and how does it have to be done?
- b. Are there other hospice staff already conducting a visit?
- c. How can hospice staff help with family visits for dying residents?

Grief Support for Residents and Family

It is likely that this environment may result in tremendous amounts of complicated grief for many people. Interventions on the front end to support, guide, minimize anger and fear, can help mitigate some of the risk factors for complicated grief. Consider how hospice's expertise with grief and bereavement counseling, especially 13-month posthumous, can be beneficial to the residents and families. Given the restrictions on family member in-person interaction, hospice staff can be helpful in ensuring frequent and consistent communication with family.

1. Assess for appropriate hospice referrals.
2. Discuss with hospice partner options for grief support for residents and families, even for non-hospice patients.
3. Once interventions have been agreed upon, provide hospice with information on family members and friends as well as best approach in communicating with them.
4. It is critical that LTC and hospice staff partner together to ensure simple, clear and supportive communication, minimizing mixed messages.

Grief Support for Staff

Staff often form close relationships and strong connections with the residents in their facilities and as such, experience grief and loss upon a resident's death. Grief support for LTC staff is beneficial during ordinary times but gains even more significance during the current crisis, as the emotional toll of multiple losses of residents, compounded by concerns for colleagues and their own family members who are sick or at risk, cannot be underestimated. Hospice can be a beneficial resource in supporting staff.

1. It is important for facility staff to talk openly about their emotions to their colleagues or other support staff.
2. Discuss with the hospice partner how grief support may be offered to staff and potential strategies for support.
 - o Hospice staff should note that facility staff are probably in the best position to offer feedback on which strategies may be most beneficial to the staff of their facility.
3. Ensure consideration of alternative methods for support versus in-person, assigning staff to facilities and minimizing entry into multiple buildings. If the movement is unavoidable, increased attention needs to be paid to infection control processes.

These are unprecedented times. We must work together in creative and supportive ways to maximize the benefits of the partnership. The threat of coronavirus to older adults and those with underlying health conditions has shown to have dire consequences, and we must do everything we can to prevent the further spread into LTC buildings.

CMS Guidance

[QSO-20-16-Hospice](#): Guidance for Infection Control and Prevention Concerning Coronavirus Disease 2019 (COVID-19) by Hospice Agencies. (March 13, 2020)

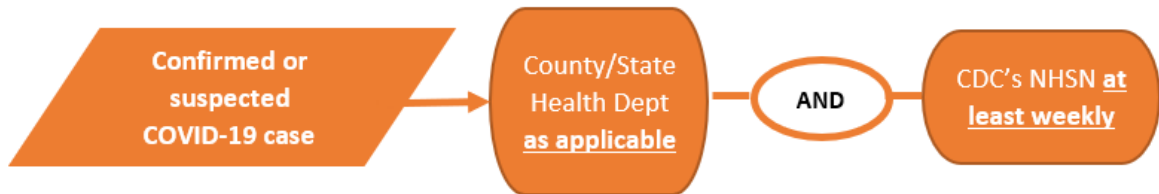
[QSO-20-14-NH](#): Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes (REVISED). (March 13, 2020)

[COVID-19 Long-Term Care Facility Guidance](#) (April 2, 2020)

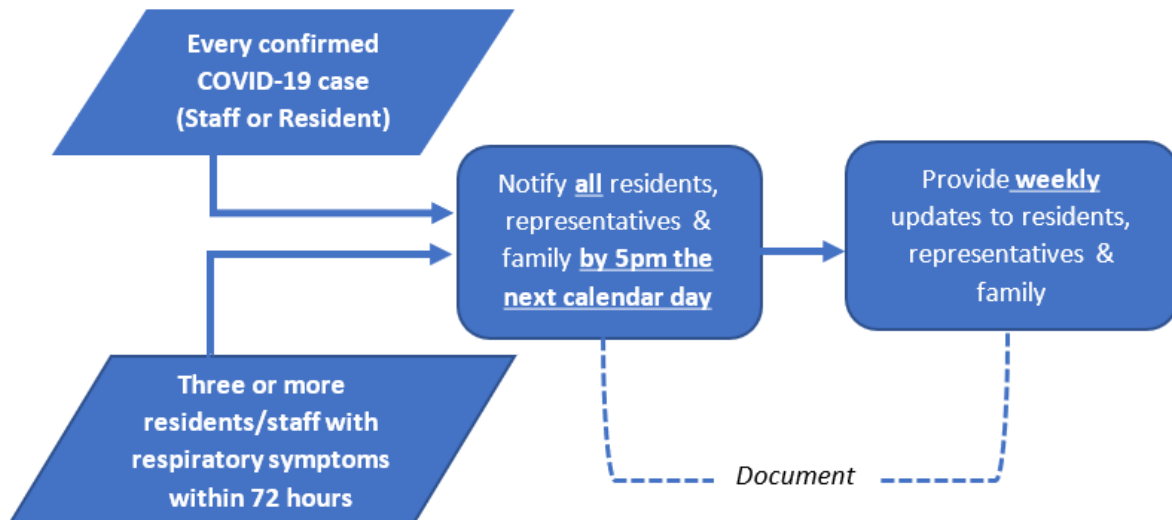
COVID-19 Reporting & Notification Guidelines for Nursing Homes

Summary Flow Charts

1. Reporting Confirmed and Suspected Cases



2. Notifying Residents and Representatives



1. Reporting Cases

- All confirmed or suspected cases of COVID-19, in addition to other required data, must be reported to CDC's National Healthcare Safety Network (NHSN) at least weekly, and to county/state health departments according to their guidelines.
- For details on NHSN Reporting, visit their [website](#).

2. Notifying Residents, Representatives, and Families

- Effective May 8, 2020, for every confirmed case of a resident or staff member AND/OR if a group of three or more residents or staff have new onset respiratory symptoms within a 72-hour period (referred to as a "cluster") the following must occur:
 - Notify residents, representatives, and families **by 5 p.m. the next calendar day** after the occurrence.
 - If you do not have any new confirmed cases or new clusters of 3 or more residents/staff with new onset respiratory symptoms within a given week, you must provide a **weekly** update.
 - Each update must include mitigation actions you are taking.
- This is a [template letter](#) you can use.

When COVID-19 is suspected or confirmed (whether resident or staff) in a nursing home, several notifications must occur.

For each resident in the nursing home who has a COVID-19 positive test (including each additional case after initial cases):

- Notify the resident, their representative, and family when they have a positive COVID-19 test.
- Notify the primary physician for the resident who has a confirmed case.
- Notify the local and state health departments with information per local/state reporting requirements.
- Notify all residents in the facility, as well as their representatives and family members **by 5 p.m. the next calendar day.**
 - This can be done by letter, website posting, listserv, recorded telephone message, or other means that make the information easily accessible.
 - The information reported must be cumulative. According to CMS, this means you must:
 - Report the total number of confirmed cases (residents/patients and staff) that have occurred in the building **since May 8, 2020** (the effective date of the new reporting requirements) at the time of the notification. This number will increase each time a new case is confirmed or remain the same if no new cases have occurred since the last reporting period. In other words, you should not remove an individual from this total if they recover or leave the facility.
 - Note: CMS's [frequently asked questions](#) on these requirements state that the facility is not required to identify new versus total cases in its reports. Whether you choose to report a single number or to identify new versus total cumulative cases is up to your preferred communication approach.
- Include information of efforts taken to mitigate the virus and any changes to normal facility operations.
- **Notifications must be done in accordance with existing privacy regulations and statute and must not include Personally Identifiable Information (PII), such as names or specific medical information.**
- This is a [template letter or script](#) you can use.
- Recommendation: Document in a log or tracking tool that required notification has been provided. Keep a record of time stamped updates to webpages, social media feeds, or recorded messages when notifications have been updated.
- Recommendation: Share the notification provided to residents, representatives and families with staff to keep them informed of the information provided.
- Include in your report as required to CDC's National Healthcare Safety Network (NHSN) at least weekly.

For each staff member of the nursing home with a COVID-19 positive test (including each additional case after initial cases):

- Notify the local and state health departments with information per state reporting requirements.
 - CDC [guidelines](#) state the health department should be notified about Health Care Professional (HCP) with symptoms of respiratory infection. Required information may vary by state.
- Notify all residents in the facility, as well as their representatives and family members **by 5 p.m. the next calendar day.**
 - This can be done by letter, website posting, listserv, recorded telephone message, or other means that make the information easily accessible.
 - The information reported must be cumulative. According to CMS, this means you must:
 - Report the total number of confirmed cases (residents/patients and staff) that have occurred in the building **since May 8, 2020** (the effective date of the new reporting requirements) at the time of the notification. This number will only increase each time a new case is confirmed or remain the same if no new cases have occurred since the last reporting period. In other words, you should not remove an individual from this total if they recover or are no longer employed by the facility.
 - Note: CMS's [frequently asked questions](#) on these requirements state that the facility is not required to identify new versus total cases in its reports. Whether you choose to report a single number or to identify new versus total cumulative cases is up to your preferred communication approach.
 - Include information of efforts taken to mitigate the virus and any changes to normal facility operations.
 - **Notifications must be done in accordance with existing privacy regulations and statute and must not include Personally Identifiable Information (PII), such as names or specific medical information.**
 - This is a [template letter or script](#) you can use.
- Recommendation: Document in a log or tracking tool that required notification has been provided.
- Recommendation: Share the notification provided to residents, representatives and families with staff to keep them informed of the information provided.
- Include in your report as required to CDC's National Healthcare Safety Network (NHSN) at least weekly.

When three or more residents or staff have new onset respiratory symptoms within 72 hours of each other:

- Notify the resident representative for each resident with new onset respiratory symptoms (resident already knows as this is the person experiencing the symptoms).
- Notify the primary physician for each resident who has new onset respiratory symptoms.

- Notify all residents in the facility, as well as their representatives and family members, **by 5 p.m. the next calendar day.**
 - This can be done by letter, website posting, listserv, recorded telephone message, or other means that make the information easily accessible.
 - According to CMS, when reporting these “clusters” you must:
 - Report by 5 p.m. the next day every time there is a new cluster (when there are three or more residents/staff with new onset respiratory symptoms within 72 hours of each other).
 - If one or more of the individuals in the cluster tests positive, report this as an increase in cumulative COVID cases in the building (prompting a report by 5 p.m. the next day).
 - Continue to report--at least weekly or whenever a subsequent occurrence of a positive case or new cluster prompts a new required report by 5 p.m. the next day--the presence of the “cluster” in the building **until one or more of the individuals in the cluster is ruled out with a negative laboratory test.** If one or more individuals in the cluster tests negative, there is no longer a cluster of 3 or more and you are no longer required to report it. You do not need to report whenever an individual who was in a cluster is ruled out. However, if a new suspected case occurs, it may create a new cluster within a subsequent 72-hour period, you then need to report that by 5 p.m. the next day and follow the same process outlined above.
 - Note: CMS’s [frequently asked questions](#) on these requirements state that the facility is not required to identify new versus total cases in its reports. Whether you choose to report a total number of current “clusters” in the building at the time of the report (until they are ruled out) or differentiate the reporting of a new cluster from an existing, previously reported cluster, is up to your preferred communication approach.
 - Include information on efforts taken to mitigate the virus and any changes to normal facility operations.
 - **Notifications must be done in accordance with existing privacy regulations and statute and must not include Personally Identifiable Information (PII), such as names or specific medical information.**
 - This is a [template letter or script](#) you can use.
- Recommendation: Document in a log or tracking tool that required notification has been provided. Keep a record of time stamped updates to webpages, social media feeds, or recorded messages when notifications have been updated.
- Recommendation: Share the notification provided to residents, representatives and families with staff to keep them informed of the information provided.
- Notify the local and state health departments with information per state reporting requirements.
 - CDC [guidelines](#) state the health department should be notified about residents with severe respiratory infection or a cluster of respiratory infections (e.g., 3 or more residents or Health Care Professional (HCP) with new-onset respiratory

symptoms over 72 hours) and of residents or HCP with symptoms of respiratory infections.

- **AHCA/NCAL NOTE:** COVID-19 would constitute a severe respiratory infection and should be reported; required information may vary by state.
- Include in your report as required by CMS to CDC's National Healthcare Safety Network (NHSN) at least weekly.

For all communications above, keep records of notifications that have been made. There is no required format, but it is important to retain documentation because CMS may take enforcement action if timely notifications are not made.