Assisted Living Facility COVID-19 Webinar Series

Episode Three: COVID-19 Infection Control Update
May 27, 2021
12:00 p.m.–1:00 p.m.
Agenda

12:00 – 12:05: Welcome

Debra Hopkins; VDH Office of Licensure and Certification (OLC) & Healthcare-Associated Infections (HAI) Team


12:20 – 12:45: COVID-19 Infection Control Update  
Dr. Rehab Abdelfattah, MD, MPH, CIC; VDH Healthcare-Associated Infections (HAI) Team  
Lisa Sollot; VDH Healthcare-Associated Infections (HAI) Team

12:45 – 12:55: Q&A for COVID-19 Infection Control Update

12:55 – 1:00: Instant Poll
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Clinical Laboratory Improvement Amendment

A Federal regulatory program ensuring quality lab testing, enforced by CMS and administered in Virginia by VDH OLC.

Facilities that examine human specimens for the diagnosis, prevention or treatment of any disease, or health assessment of human beings is considered a laboratory and must meet CLIA requirements. These facilities must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

COVID tests and Home Use Authorization:
A CLIA Certificate is not required of individuals self-collecting swabs and performing these at-home COVID test when in their private residence. These same tests when used in a patient care setting, require a CLIA Certificate of Waiver.
A CLIA Certificate of Waiver is a type of certificate issued by CLIA. Facilities that have a CLIA Certificate of Waiver can perform tests that are classified as CLIA Waived by the FDA or have a FDA EUA for a waived testing environment.

Do I already have a CLIA Certificate?
CMS CLIA lab look up at: https://qcor.cms.gov/main.jsp

How do I apply for a CLIA Certificate?
CMS 116: CLIA Application for Certification
In the next three sections, indicate testing performed and annual test volume.

**VI. WAIVED TESTING**

- **Appllying for a Certificate of Waiver:** Complete the entire section and step sections vi (waiver testing) and vii (non-waived testing).

  Identify the waived testing to be performed. Be as specific as possible. This includes each analysis test system or device used in the laboratory.  
  - e.g., (Rapid Drug, Acute Home Glucose Meter)

**VII. PPM TESTING**

- **Applying for a Certificate for PPM:** Complete this section and skip section vii (non-waived testing).

  Identify the PPM testing to be performed. Be as specific as possible.  
  - e.g., (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

**IX. TYPE OF CONTROL**

(check the one most descriptive of ownership type)

- **VOLUNTARY NONPROFIT**
- **FOR PROFIT**
- **GOVERNMENT**
  - 01 Religious Affiliation
  - 02 Private Nonprofit
  - 03 Other Nonprofit
  - 04 Proprietary
  - 05 City
  - 06 County
  - 07 State
  - 08 Federal
  - 09 Other Government

**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

- **CLIA NUMBER**
- **NAME OF LABORATORY**

**ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SINGING APPLICATION**

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined not more than $10,000, or both, except that if the violation is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years and/or fined in accordance with Title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory’s eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

**SIGNATURE OF OWNER/DIRECTOR OF LABORATORY**

Print Name of Owner/Director of Laboratory

Date

**NOTE:** Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.
Mail (overnight delivery recommended) the signed original CMS116 to our office at:

Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, VA 23233-1485

No money is due with the application. Once you get your CLIA number, the $180 fee can be paid the next day on-line at pay.gov
For Waived COVID testing:

Follow Manufacturer Instructions,
Document training,
Document temperature monitoring of kit storage and testing areas,
Report test results to the VDH or HHS.

CLIA inquiries can be emailed to:
CLIALAB@vdh.virginia.gov
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Infection Control Guidance Updates

The Interim Public Health Recommendations for Fully Vaccinated People, posted May 13, 2021 found [here](#), that fully vaccinated people no longer need to wear a mask or physically distance in any setting,

✓ **Do not apply to healthcare settings** - staff, patients, residents, and visitors should continue to wear masks as recommended in all healthcare facilities.

✓ **Healthcare settings** refers to places where healthcare is delivered and includes, but is not limited to, acute care facilities, long term acute care facilities, inpatient rehabilitation facilities, nursing homes and assisted living facilities, home healthcare, vehicles where healthcare is delivered (e.g., mobile clinics), and outpatient facilities, such as dialysis centers, physician offices, and others.

✓ Healthcare facilities should continue to refer to the Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination for recommendations regarding source control and physical distancing in healthcare settings.
Infection Control Guidance Updates–cont’d.

Highlights from CDC’s, Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination, updated 4/27/2021

Communal Activities and Dining:

• Fully vaccinated patients/residents can participate in communal dining without use of source control or physical distancing.

• If unvaccinated patients/residents are dining in a communal area (e.g., dining room) all patients/residents should use source control when not eating and unvaccinated patients/residents should continue to remain at least 6 feet from others.

• If vaccination status cannot be determined, the safest practice is for all participants to follow all recommended infection prevention and control practices including maintaining physical distancing and wearing source control.

Healthcare Personnel:

In general, fully vaccinated HCP should continue to wear source control while at work. However, fully vaccinated HCP could dine and socialize together in break rooms and conduct in-person meetings without source control or physical distancing. If unvaccinated HCP are present, everyone should wear source control and unvaccinated HCP should physically distance from others.
Infection Control Guidance Updates—cont’d.

Work restriction for asymptomatic HCP and quarantine for asymptomatic patients/residents:

- Fully vaccinated HCP with higher-risk exposures who are asymptomatic do not need to be restricted from work for 14 days following their exposure.

However, HCP who have traveled should continue to follow CDC travel recommendations and requirements

- Fully vaccinated in-patients and residents in healthcare settings should continue to quarantine following prolonged close contact (within 6 feet for a cumulative total of 15 minutes or more over a 24-hour period) with someone with SARS-CoV-2 infection; outpatients should be cared for using recommended Transmission-Based Precautions

- Quarantine is no longer recommended for residents who are being admitted to a post-acute care facility if they are fully vaccinated and have not had prolonged close contact with someone with SARS-CoV-2 infection in the prior 14 days.
Infection Control Guidance Updates—cont’d.

SARS-CoV-2 Testing:

• Anyone with symptoms of COVID-19, regardless of vaccination status, should receive a viral test immediately.

• Asymptomatic HCP with a higher-risk exposure and patients or residents with prolonged close contact with someone with SARS-CoV-2 infection, regardless of vaccination status, should have a series of two viral tests for SARS-CoV-2 infection. In these situations, testing is recommended immediately and 5–7 days after exposure.

• People with SARS-CoV-2 infection in the last 90 days do not need to be tested if they remain asymptomatic, including those with a known contact.

• In healthcare facilities with an outbreak of SARS-CoV-2, recommendations for viral testing HCP, residents, and patients (regardless of vaccination status) remain unchanged.
Infection Control Guidance Updates—cont’d.

What trigger testing in LTCFs?

1- When a symptomatic individual is identified: test staff and residents vaccinated and unvaccinated, with signs and symptoms must be tested

2- Outbreak: test all staff and residents, vaccinated and unvaccinated, that previously tested negative until no new cases are identified

3- Routine testing of asymptomatic HCP (for healthcare facilities that are performing screening testing):

- unvaccinated HCP should continue expanded screening testing.
- for asymptomatic HCP who do not have a known exposure, vaccinated HCP can be excluded from such a testing program.
## Quarantine Recommendations in Healthcare Settings

<table>
<thead>
<tr>
<th>HCPs</th>
<th>Patients/Residents</th>
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<tbody>
<tr>
<td>Unvaccinated HCP who have traveled domestically or internationally</td>
<td>Fully vaccinated residents and inpatients in health care setting should continue to quarantine following an exposure to someone with COVID-19</td>
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<td>Unvaccinated residents newly admitted or re-admitted to a post-acute care facility</td>
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<td>For unvaccinated residents leaving the facility for ≥ 24 hours</td>
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• Quarantine is currently not required for residents, regardless of vaccination status, leaving the facility for less than 24 hours who are asymptomatic and have not had close contact with someone infected with SARS-CoV2. However, facilities might consider quarantining residents based on an assessment of risk, uncertainty exists about adherence or adherence of those around them to recommended IPC practices.
Visitations Scenarios

Scenario # 1
Residents who are infected with COVID-19 or residents who are in quarantine:
Indoor visitation limited to compassionate care for vaccinated and unvaccinated residents.
Visitations Scenarios- cont.

Scenario # 2
COVID-19 county positivity rate is >10% and ≤ 70% of residents are fully Vaccinated:
Indoor visitation for **unvaccinated residents** should be limited solely for compassionate care
Visitations Scenarios - cont.

Scenario # 3
When an outbreak occurs (a single new case of COVID-19 in a HCP or a new facility onset case in a resident):
Facility should immediately begin outbreak testing and suspend all visitation. If the first round of outbreak testing reveals NO additional COVID-19 cases in other areas of the facility visitation can be resumed in areas with NO COVID-19 cases. HOWEVER, the facility should suspend visitation on the affected unit until the facility meets the criteria to discontinue outbreak testing (14 days with no new cases). If new cases are identified on the first round of testing in other areas indoor visitation should be suspended for all residents until the facility meets criteria to discontinue outbreak testing.
Visitations Scenarios—cont.

Scenario # 4

When a resident shares a room:

Visits for residents who share a room should ideally not be conducted in the resident’s room.

If in-room visitation must occur an unvaccinated roommate should not be present during the visit.

Residents and visitors should physically distance from other residents and HCP in the facility.

Outdoor visitation is preferred even when the resident and visitor are fully vaccinated. Outdoor visits generally pose a lower risk of transmission due to increased space and air flow.
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1. How helpful was the information presented in this webinar?

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<td>Extremely helpful</td>
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