Post-vaccination Testing to Identify Vaccine Breakthrough Cases and Track SARS-CoV-2 Variants in Long-term Care Facilities

This document applies only to long-term care facilities licensed by the Oregon Department of Human Services.

Rationale

Oregon Health Authority (OHA) is working with the Centers for Disease Control and Prevention to identify vaccine breakthrough cases and SARS-CoV-2 variants in long-term care facilities (LTCFs). Currently authorized COVID-19 vaccines are highly, but not 100%, effective against COVID-19 illness. Therefore, it is expected that some COVID-19 cases will occur among people who are fully vaccinated against COVID-19. While a vaccine breakthrough case may indicate a SARS-CoV-2 variant, not all vaccine breakthrough cases are caused by SARS-CoV-2 variants.

Tracking of vaccine breakthrough infections provides signals regarding:

- Sub-optimal immune response in residents of LTCFs
- Waning immunity
- Viral variants that may impact vaccine effectiveness
- Vaccine compromise due to inadequate cold-chain or other issues during shipping, storage, or administration

A **vaccine breakthrough case** is defined as a U.S. resident who has:

- SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after completing the primary series of an FDA-authorized COVID-19 vaccine, where date of final vaccine dose = day 0;

AND

- Not had SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected <45 days before the most recent positive test.

SARS-CoV-2 variants are expected to occur over time because viruses constantly change through mutation. Multiple SARS-CoV-2 variants have been documented globally. There are currently three classes of SARS-CoV-2 variants: variant of interest, variant of concern, and variant of high consequence. Currently, there are no SARS-CoV-2 variants of high consequence. A number of variants of concern have been documented in the U.S. and are closely monitored and characterized by federal agencies. Some of these variants are more transmissible or associated with more severe disease, while others are not as affected by antibodies from prior infection, vaccination, or some monoclonal antibodies. More information about variants can be found here.

Specimen collection and testing

Investigation of vaccine breakthrough cases and identification of SARS-CoV-2 variants require viral sequencing and culture. For this to occur, additional respiratory specimens may need to be collected in viral transport media (VTM). VTM can be requested from the local public health authority (LPHA).

OHA is actively working with clinical laboratories in Oregon on standards for specimen processing and storage to optimally detect vaccine breakthrough cases and SARS-CoV-2 variants, so that labs other than the Oregon State Public Health Laboratory (OSPHL) can perform some of this testing in the future. Until these standards are in place, follow the instructions below.

1. **Surveillance testing** of staff for COVID-19 should continue with the facility's contracted clinical laboratory.
2. For the **first confirmed COVID-19 case(s)** identified ≥ 14 days after the facility's second COVID-19 vaccination clinic:
    a. If the first case(s) are identified by point-of-care antigen testing, the facility should collect a respiratory specimen within 48 hours of the positive antigen test, regardless of the vaccination status of the case(s). The specimen should be sent to OSPHL for PCR testing. Ideally, specimen should be collected in viral transport media (VTM), which will allow for both viral sequencing and culture. Facility may use test kits it has on hand if securing VTM test kits results in delayed specimen collection.
    b. If the first case(s) meet the vaccine breakthrough definition AND are identified by molecular testing at a laboratory other than OSPHL, collection of a respiratory specimen is not recommended. This is because the typical turnaround time for clinical laboratories is > 48 hours, and therefore, the viral load is often too low for viral sequencing and culture.
    c. If the first case(s) do not meet the vaccine breakthrough definition AND are identified by molecular testing at a laboratory other than OSPHL, collect a respiratory specimen within 48 hours of receiving the positive test result. The specimen should be sent to OSPHL for PCR testing and sequencing. In this scenario, the specimen does not need to be collected in VTM.
3. For **outbreak-associated testing** in facilities ≥ 14 days after the facility's second COVID-19 vaccination clinic:
    a. Coordinate with the LPHA to have facility-wide testing completed at OSPHL. Specimens should be collected in VTM.
    b. Testing at OSPHL should occur even if the first case(s) identified in the facility do not meet the vaccine breakthrough definition.
4. Once outbreak-associated testing has been completed, routine surveillance testing of staff for COVID-19 should return to the facility's contracted clinical laboratory.