

## COVID-19 Viral Testing

Jessica Niculcea, Pharm.D. Clinical Pharmacist Specialist, Providence Health Plan and Kathy Sentena, Pharm.D., OSU Drug Use Research and Management Group

SARS coronavirus 2 (SARS-CoV-2), more commonly known as coronavirus disease (COVID-19), has impacted the people of Oregon with over 36,000 total cases and over 600 deaths reported as of October 2020.<sup>1</sup> Testing for this virus is critical for case identification to slow the disease spread and ensure infected persons are triaged to receive appropriate patient care. Fortunately, testing for COVID-19 has become more accessible for individuals as the COVID-19 pandemic has persisted. However, confusion still exists for many patients and practitioners regarding COVID-19 testing recommendations. The focus of this newsletter is to clarify who should be tested, timing of tests and where to receive the COVID-19 test in Oregon.

### COVID-19 Testing Approval

The Oregon Health Authority (OHA) recommends using only tests that have emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA). On February 4<sup>th</sup>, 2020 the Department of Health and Human Services issued an EUA under the Public Readiness and Emergency Preparedness Act (PREP). This EUA allows for unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious disease, in this case COVID-19.<sup>2</sup> Technologies and therapies under EUA have not undergone full FDA scrutiny and these authorizations are not FDA-approvals. Likely, once the COVID-19 pandemic is declared over, the EUA will expire as seen in the EUA expiration of peramivir in 2010 after the 2009 H1N1 influenza pandemic.<sup>3</sup> Additionally, the EUA could be revoked if deemed appropriate by the FDA.

### Types of COVID-19 Tests

Three types of tests are available for COVID-19: viral tests (e.g., molecular based and antigen tests) and serologic (antibody) tests. A viral tests tells individuals if they have a current infection with COVID-19, while an antibody test might tell individuals if they have had a past infection.<sup>4</sup> Antibody testing is occurring at certain locations around Oregon, however, the OHA states there is insufficient evidence to suggest that antibody tests are a reliable indicator that an individual has or had COVID-19 or that they have immunity.<sup>5</sup> Therefore, COVID-19 testing referenced in the remainder of this article will refer to viral testing, as there is uncertainty with antibody testing.

Viral tests can be conducted via one of two technologies: a molecular test or an antigen test.<sup>6</sup> Molecular tests detect viral ribonucleic acid (RNA) via reverse transcription polymerase chain reaction (RT-PCR) process and is considered the

gold standard. The second method is rapid antigen testing which detects the presence of the nucleocapsid protein antigen. Both test detect active viral COVID-19 infection. Viral testing using RT-PCR provides results in less than an hour to more than 2 days.<sup>4</sup> Rapid antigen tests take approximately 15 minutes but are less sensitive than molecular assays. Rapid antigen testing is most accurate in the early stages of infection, when there is higher viral loads. Rapid antigen testing may require confirmation with RT-PCR within 2 days as a confirmatory test.<sup>6</sup> Both of these tests, antigen and molecular, can be conducted as either a point-of-care (POC) test or lab processed test.<sup>7</sup>

Accuracy of the testing methods is determined by sensitivity and specificity. The *sensitivity* of a test refers to the ability of the test to correctly identify those with a disease compared with *specificity*, which allows a test to identify those patients without disease. A recent Cochrane review found the average sensitivity of the antigen tests to be 56.2% (95% confidence interval [CI], 29.5% to 79.8%) with an average specificity of 99.5% (95% CI, 98.1% to 99.9%).<sup>8</sup> Sensitivity for the molecular assay test was higher with an average sensitivity of 95.2% (95% CI, 86.7% to 98.3%) and specificity of 98.9% (95% CI, 97.3% to 99.5%).<sup>8</sup> The evidence was found to be at high risk of bias with an emphasis on the need for additional trials.

### Testing Collection Methods

It is recommended that nasopharyngeal, mid-turbinate (MT) or nasal swabs be utilized for testing versus other testing collection methods. Accuracy of recommended collection sites range from 75% to 95% and are displayed in **Table 1**.<sup>6</sup> Oral tests were 56% sensitive and saliva tests were 85% sensitive (and inconsistent); therefore, these testing sites are currently not preferred.<sup>6</sup> Collection by the patient or healthcare worker was deemed appropriate for nasal and MT testing. Due to the quality of studies available, the certainty of the evidence is very low.

**Table 1. Accuracy of COVID-19 Results based on Collection Site<sup>\*6</sup>**

	Nasal	Nasopharyngeal	Mid-turbinate
Sensitivity (95% CI)	76% (59% to 94%)	97% (92% to 100%)	100% (93% to 100%)
Specificity (95% CI)	100% (99% to 100%)	100% (99% to 100%)	100% (99% to 100%)

Key: \* Bases on estimates of positive and negative test results in a hypothetical population of 1000 individuals

**Timing of Testing**

Close contacts of confirmed or presumptive COVID-19 cases are recommended to be tested 3-14 days after exposure, although the optimal time for testing remains unknown.<sup>9</sup> Recommendations for the timing of testing for other populations are as follows:<sup>6</sup>

- Symptomatic individuals: tested as soon as possible.
- Patients undergoing surgery: ideally 48-72 hours before surgery.
- Patients undergoing immunosuppressive procedures: ideally 48-72 hours before procedure.

If suspicion is low for COVID-19 the Infectious Diseases Society of America (IDSA) recommends not repeating the test if results are negative; however, the test should be repeated in light of a negative test result if the patient is hospitalized or at high suspicion of having COVID-19.<sup>6</sup> Repeat testing should take place within 24-48 hours of a negative test result if an individual is an appropriate candidate for repeat testing.<sup>6</sup> If a patient tests positive, there is no need to retest for at least 3 months.<sup>6</sup>

**Recommendations for Who Should be Tested**

OHA published updates in October for COVID-19 recommendations relating to viral testing for individuals with symptoms (Table 2) and without symptoms (Table 3).<sup>9</sup> Additional guidance on who should receive testing if resources are limited is available on the OHA website.<sup>9</sup> Per the Centers for Disease Control and Prevention (CDC), COVID-19 symptoms may appear 2-14 days after exposure to the virus.<sup>10</sup> Additionally, OHA recently recommends that close contacts of confirmed or presumptive COVID-19 cases, people exposed to COVID-19 in a congregate setting, and migrant/seasonal agricultural workers upon arrival in Oregon be tested for COVID-19 regardless of whether they have symptoms or not.<sup>9</sup> Clinicians may order commercial tests based on their clinical judgement.

**Table 2. OHA Recommendations for COVID-19 viral testing for any person with new onset of a COVID-19 –like illness which includes, but not limited to:<sup>9</sup>**

<ul style="list-style-type: none"> <li>• <b>Fever or chills</b></li> <li>• <b>Shortness of breath or difficulty breathing</b></li> <li>• <b>Headache</b></li> <li>• <b>New loss of taste or smell</b></li> <li>• <b>Congestion or runny nose</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Cough</b></li> <li>• <b>Fatigue</b></li> <li>• <b>Muscle or body aches</b></li> <li>• <b>Sore throat</b></li> <li>• <b>Nausea or vomiting</b></li> <li>• <b>Diarrhea</b></li> </ul>
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**Table 3. OHA Recommendations for COVID-19 viral testing for people without symptoms of a COVID-19-like illness limited to the following groups:<sup>9</sup>**

- **People who identify as Black, African-American, Latino, Latina, Latino, American Indian/Alaska Native, Asian, Asian American or Pacific Islander**
- **People who identify as having a disability**
- **People whose first language is not English**

**COVID-19 Testing is available to all Oregon Health Plan (OHP) members at no cost<sup>12</sup>**

**Interpreting COVID-19 Test Results to Patients**

OHA has provided messaging for providers to utilize with patients regarding the accuracy of COVID-19 viral tests and antibody tests (Figure 1 and Figure 2).<sup>9</sup> Patients should be considered non-contagious if it has been at least 10 days since symptom onset and fever free for at least 24 hours. If a patient has been in close contact with someone with COVID-19 and tests negative, they should still self-isolate for at least 14 days.<sup>11</sup>

**Figure 1. Test Results and Accuracy Limitations - messaging for patients with symptoms of COVID-19<sup>9</sup>**

Messaging to patients with symptoms of COVID-19		
	Viral test	Antibody test
<b>Positive</b>	You have COVID-19. Protect your community by isolating according to public health recommendations.	Approximately half of test results may be falsely positive.* Even if you do have antibodies, it's not yet known whether they provide protection against reinfection.
<b>Negative</b>	Tests are falsely negative in about 30% of patients with symptoms. Assume that you have COVID-19 and protect your community by isolating until you feel better.	Your symptoms may be caused by an illness that is not COVID-19. Results may also be falsely negative even if you have or had COVID-19. Antibody tests may not become positive for weeks following infection.

**Figure 2. Test Results and Accuracy Limitations - messaging for patients without symptoms of COVID-19<sup>9</sup>**

Messaging to patients without symptoms of COVID-19		
	Viral test	Antibody test
<b>Positive</b>	You have COVID-19. You may or may not develop symptoms. Protect your community by isolating according to public health recommendations.	Approximately half of test results may be falsely positive.* Even if you do have antibodies, it's not yet known whether they provide protection against reinfection.
<b>Negative</b>	You may have COVID-19. Tests may be falsely negative, and a negative result provides no indication that you are protected from infection.	Results may be falsely negative even if you have or had COVID-19. Antibody tests may not become positive for weeks following infection.

\* False positive rate depends on the specificity of the test used and the prevalence of COVID-19 in the community.

**Where to Direct Individuals for Testing**

OHA recommends individuals contact their primary healthcare provider or clinic if they believe they need testing. For individuals without a doctor, OHA has a phone number, 211,

that will provide individuals with help for finding nearby clinics that test for COVID-19.<sup>12</sup> Additionally, the OHA website has a COVID-19 test site finder map that individuals can utilize by submitting their address, ZIP code, or city and a list of nearby COVID-19 testing sites will populate.<sup>13</sup> Sites listed include clinics, urgent care sites, and pharmacies that test for COVID-19. Providers and other individuals can contribute to the map by submitting a new location that tests for COVID-19 on the interactive map. New locations are reviewed and the map is usually updated within 12 hours with the new location.<sup>13</sup> Additionally, patients may be directed to their respective county website which lists COVID-19 testing sites in their region.

Oregon COVID-19 Testing Sites can be found at:  
<https://govstatus.egov.com/or-oha-covid-19-testing>

For testing sites in Oregon, the majority require appointments to be made ahead of time. This may prove to be difficult for patients who are not established with a primary care provider, do not have a phone, or do not have internet access to schedule an appointment. Two organizations that are currently accepting individuals for COVID-19 testing with no appointment required are:<sup>14,15</sup>

Oregon Health and Science University (OHSU):  
<https://www.ohsu.edu/health/coronavirus-resources#section-1117926>

Virginia Garcia Medical Center (select events):  
<https://viriniagarcia.org/coronavirus/>

### Pharmacy Testing Sites

Some of the most convenient locations for patients to receive COVID-19 testing include pharmacies. Rite Aid and Walgreens have COVID-19 testing sites provided at no cost. Rite Aid currently has 17 locations and Walgreens has 2 locations performing COVID-19 tests in Oregon.<sup>16,17</sup> Safeway and Albertsons are also offering testing at pharmacies but for an approximate cost of \$140 each.

Rite Aid: <https://www.riteaid.com/pharmacy/services/covid-19-testing>.

Walgreens: <https://www.walgreens.com/findcare/covid19/testing>

Patients can access testing by completing a screening survey online to determine eligibility, receive an appointment for testing, have the test performed by the patient or pharmacist using a nasal swab, and have test results relayed back to the patient via email or phone call.<sup>16,17</sup>

### The Role of the Provider

Information regarding COVID-19 testing changes rapidly. In order to provide accurate information and minimize confusion, it is paramount that providers stay up to date on information regarding COVID-19 testing. Providers and patients can utilize reliable sources of information for COVID-19 testing, such as,

the OHA and CDC. In this way, accurate and optimal patient care can be provided to the individuals of Oregon.

Additional information on Coronavirus Management can be found at

<https://pharmacy.oregonstate.edu/drug-policy/newsletters/coronavirus-management>

Peer Reviewed By: James Lewis, Pharm.D., FIDSA, Clinical Supervisor for Infectious Disease, Oregon Health and Science University, Portland, Oregon

### References:

1. COVID-19 Updates. Oregon Health Authority. Available at: <https://govstatus.egov.com/OR-OHA-COVID-19>. Last accessed on October 9, 2020.
2. Declaration Under The Public Readiness And Emergency Preparedness Act For Medical Countermeasures Against COVID-19. Federal Register. Available at: <https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>. Last accessed on October 6, 2020.
3. Emergency Use Authorization Of Peramivir IV Fact Sheet For Health Care Providers. United States Food & Drug Administration. Available at: <https://www.fda.gov/media/77787/download>. Last accessed on October 6, 2020.
4. COVID-19 Testing Overview. Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>. Last accessed on October 9, 2020.
5. Antibody Testing: What We Know Right Now. Oregon Health Authority. Available at: <https://govstatus.egov.com/or-oha-covid-19-testing>. Last accessed on October 9, 2020.
6. Hanson K, Caliendo A, Arias C, et al. Infectious Disease Society of America Guidelines On The Diagnosis Of COVID-19. *Infectious Disease Society of America*. Available at: <https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/>. Last accessed on October 19, 2020.
7. Coronavirus Testing Basics. United States Food & Drug Administration. Available at: <https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics>. Last accessed on October 9, 2020.
8. Dines J, Deeks JJ, Adriano A, et al. Rapid, Point-of-care Antigen and Molecular-based Tests for Diagnosis of SARS-CoV-2 Infection (Review). *Cochrane Database of Systematic Reviews*. 2020; Issue 8. Art. No.: CD013705.
9. COVID-19 testing recommendations for health care providers. Oregon Health Authority. Available at: <https://shredsystems.dhsoha.state.or.us/DHSForms/Served/le2267.pdf>. Last accessed on October 9, 2020.
10. Symptoms of coronavirus. Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>. Last accessed on October 9, 2020.
11. Duration of Isolation and Precautions for Adults with COVID-19. Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>. Last accessed on November 5, 2020.
12. Oregon Health Plan and the Novel Coronavirus (COVID-19). Oregon Health Authority. Available at: <https://www.oregon.gov/oha/HSD/OHP/Pages/ohp-covid-19.aspx>. Last accessed on October 9, 2020.
13. COVID-19 Testing in Oregon. Oregon Health Authority. Available at: <https://govstatus.egov.com/or-oha-covid-19-testing>. Last accessed on October 6, 2020.
14. OHSU Drive-up Testing. Oregon Health and Science University. Available at: <https://www.ohsu.edu/health/coronavirus-resources#section-1117926>. Last accessed on October 6, 2020.
15. COVID-19 What You Need To Know. Virginia Garcia Memorial Health Center. Available at: <https://viriniagarcia.org/coronavirus/>. Last accessed on October 6, 2020.

16. COVID-19 Testing Available. RiteAid. Available at: <https://www.riteaid.com/pharmacy/services/covid-19-testing>. Last accessed on October 6, 2020.
17. COVID-19 Testing. Walgreens. Available at: <https://www.walgreens.com/findcare/covid19/testing>. Last accessed on October 6, 2020.