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**TEMPORARY ADMINISTRATIVE ORDER**  
INCLUDING STATEMENT OF NEED & JUSTIFICATION

**PH 25-2020**  
CHAPTER 333  
OREGON HEALTH AUTHORITY  
PUBLIC HEALTH DIVISION

**FILED**  
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SECRETARY OF STATE  
& LEGISLATIVE COUNSEL

FILING CAPTION: Emergency Rule for COVID-19 Testing at Waived Laboratories

EFFECTIVE DATE: 04/23/2020 THROUGH 10/19/2020

AGENCY APPROVED DATE: 04/23/2020

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**NEED FOR THE RULE(S):**

The Oregon Health Authority (Authority), Public Health Division, Laboratory Compliance section is adopting a temporary rule in chapter 333, division 24, pertaining to COVID-19 testing at waived laboratories. The temporary rule permits a waived laboratory and a pharmacy or a pharmacy sponsored facility that has a waived laboratory license (certificate of waiver) to perform COVID-19 testing as defined in the rule. In addition, it permits a pharmacist that is employed by or contracts with a pharmacy or a pharmacy sponsored facility with a waived laboratory license to perform COVID-19 tests as identified in the rule to screen patients for COVID-19 tests, order and administer COVID-19 tests for patients and report the results of COVID-19 tests. Lastly, the rule outlines requirements that a person performing COVID-19 testing as permitted under the rule must follow. This will increase Oregon's COVID-19 testing capacity and support the state's COVID-19 response. Robust testing in Oregon is crucial to Oregon's ability to fight the spread of the disease, and this temporary rule will allow waived pharmacies to do certain COVID-19 testing, which they cannot do under the current rules. Waived laboratories are required to report test results to a patient's primary care provider and to state and local public health authorities.

**JUSTIFICATION OF TEMPORARY FILING:**

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and the public. These rules need to be adopted promptly so that waived laboratories and pharmacies or pharmacy sponsored facilities that have waived laboratory licenses can perform COVID-19 testing for Oregonians (qualitative detection of nucleic acid from SARS-CoV-2) as authorized by the U.S. Federal Drug Administration Emergency Use Authorizations for the ID NOW COVID-19, Xpert Xpress SARS-CoV-2 and Accula SARS-CoV-2 Test devices as outlined in the rules. In addition, this rule permits pharmacists who are employed by or contract with a pharmacy or a pharmacy sponsored facility that has a waived laboratory license to perform COVID-19 tests as identified in the rule to screen patients for COVID-19 tests, order and administer COVID-19 tests for patients and report the results of COVID-19 tests. This will increase Oregon's COVID-19 testing capacity and support the state's COVID-19 response. Robust testing in Oregon is crucial to Oregon's ability to fight the spread of the disease, and this temporary rule will allow waived pharmacies to do certain COVID-19 testing, which they cannot do under the current rules. Waived laboratories are required to report test results to a patient's primary care provider and to state and local public health authorities.

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DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

U.S. Federal Drug Administration Emergency Use Authorizations: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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ADOPT: 333-024-3000

RULE TITLE: Emergency Rule for COVID-19 Testing at Waived Laboratories

RULE SUMMARY: Temporary adoption of OAR 333-024-3000 - "Emergency Rule for COVID-19 Testing at Waived Laboratories": Permits a waived laboratory and a pharmacy or a pharmacy sponsored facility that has a waived laboratory license (certificate of waiver) to perform qualitative detection of nucleic acid from SARS-CoV-2 as authorized by U.S. Federal Drug Administration Emergency Use Authorizations (EUA) for the ID NOW COVID-19, Xpert Xpress SARS-CoV-2 and Accula SARS-CoV-2 Test devices. In addition, permits a pharmacist that is employed by or contracts with a pharmacy or a pharmacy sponsored facility with a waived laboratory license to perform COVID-19 tests as identified in the rule to screen patients for COVID-19 tests, order and administer COVID-19 tests for patients and report the results of COVID-19 tests. Lastly, it outlines requirements a person permitted to perform COVID-19 testing as specified in the rule must follow.

RULE TEXT:

(1) The purpose of this rule is to permit:

(a) A waived laboratory to perform COVID-19 testing as identified in this rule.

(b) A pharmacy or a pharmacy sponsored facility that has a waived laboratory license (certificate of waiver) issued by the Oregon Health Authority under ORS 438.110(1)(d) to perform COVID-19 testing as identified in this rule.

(c) A pharmacist who is employed by or who contracts with a pharmacy or a pharmacy sponsored facility that has a waived laboratory license to perform COVID-19 tests as identified in this rule, to screen patients for COVID-19 tests, order and administer COVID-19 tests for patients, and report the results of COVID-19 tests.

(2) For purposes of this rule the following definitions apply:

(a) "COVID-19 test" or "COVID-19 testing" means qualitative detection of nucleic acid from SARS-CoV-2 as authorized by the following U.S. Federal Drug Administration Emergency Use Authorizations (EUA):

(A) EUA dated April 21, 2020, issued to Abbott Diagnostics Scarborough, Inc., for the ID NOW COVID-19 device, and any previously issued EAUs for this device.

(B) EUA dated April 10, 2020, issued to Cepheid, for the Xpert Xpress SARS-CoV-2 device, and any previously issued EUAs for this device.

(C) EUA dated March 23, 2020, issued to Mesa Biotech Inc., for the device Accula SARS-CoV-2 Test device.

(b) "Pharmacist" has the meaning given that term in ORS 689.005.

(c) "Pharmacy" has the meaning given that term in ORS 689.005.

(d) "Waived laboratory" has the meaning given that term in OAR 333-024-0010.

(3) A person permitted under this rule to perform COVID-19 testing must:

(a) Obtain from each patient, the name and contact information for the patient's primary care provider (PCP). If the patient does not have a PCP or refuses to provide that information, that must be documented by the waived laboratory.

(b) Follow and comply with the manufacturer's product insert and other instructions for performing the COVID-19 tests, and any requirements of the EUA for the device.

(c) Comply with OAR 333-024-0016(1).

(d) Maintain for two years:

(A) Test results in accordance with OAR 333-024-0050(2); and

(B) Records that show compliance with subsection (b) of this section.

(e) Report all test results to:

(A) The patient and the patient's PCP.

(B) The state or local public health authority as specified in OAR 333-018-0900.

STATUTORY/OTHER AUTHORITY: ORS 438.110, 438.450, 438.120

STATUTES/OTHER IMPLEMENTED: ORS 438.010 - 438.510