

## COVID-19 Testing for Pharmacies in WV

### **Purpose**

On April 8, 2020, the United States Department of Health and Human Services (HHS) published a [guidance](#) to authorize licensed pharmacists to order and administer COVID-19 tests, including serology authorized by the Food and Drug Administration (FDA). A current list of the FDA authorized tests used to diagnose and respond to public health emergencies under the Emergency Use Authorization (EUA) are available [here](#) under In Vitro Diagnostic EUAs.

The FDA clearly specifies which point-of-care tests for COVID-19 are considered CLIA-waived according to an EUA. As defined, CLIA-waived tests are “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.” The FDA determines which tests meet these criteria when it reviews the manufacturer’s application for a waiver. Pharmacies are readily available in our community and can play a role in testing and response. Below are two pathways for pharmacies to assist and participate in the COVID-19 response.

### **Pathways**

Pathway 1 – <b><u>Specimen Only</u></b>	Pathway 2 – <b><u>Point-of-Care</u></b>
Pharmacist collects specimen or aids in self-collection of the specimen; specimen is sent to a laboratory for testing.	Pharmacist collects specimen or aids in self-collection of the specimen; specimen is tested by the pharmacy using a point of care test.

### **Checklist**

Testing Services	
Pathway 1	Pathway 2
<input type="checkbox"/> The licensed pharmacist has been given the authority to order and administer COVID-19 tests by <a href="#">HHS*</a> . Pharmacist could also have a local physician standing order or individual prescription authorizing the test. <input type="checkbox"/> Pharmacy has contracted with a laboratory for testing that will report results electronically.	<input type="checkbox"/> Pharmacy has an active CLIA Certificate of Waiver

Testing Supplies	
Pathway 1	Pathway 2
<input type="checkbox"/> Pharmacy has obtained specimen collection kits including specimen swabs and viral transport media. <i>Pharmacy should work with contracted lab to obtain supplies.</i>	<input type="checkbox"/> Pharmacy has obtained the point-of-care testing machine and cassettes. <input type="checkbox"/> Pharmacy has obtained the specimen collection kits. <input type="checkbox"/> Pharmacy employees have been trained on the testing machine.

Personal Protective Equipment (PPE)
Both Pathways
<input type="checkbox"/> <a href="#">CDC Infection Prevention Guidelines</a> have been reviewed. <input type="checkbox"/> <a href="#">CDC Specimen Collection, Handling, and Testing Guidelines</a> have been reviewed with emphasis on PPE required depending on the type of specimen collection occurring. <input type="checkbox"/> Pharmacy has obtained adequate PPE. <i>Pharmacy will need to be able to supply their own PPE. Public supplies are not currently available.</i>

☐ Pharmacy employees have been trained on appropriate PPE use including storage, disposal/recycling, fit testing on N95 respirators.

Specimen Collection	
Pathway 1	Pathway 2
<input type="checkbox"/> <a href="#">CDC Specimen Collection Guidelines</a> have been reviewed. <input type="checkbox"/> Pharmacy has received guidance from contracted laboratory on accepted specimen type. <input type="checkbox"/> Pharmacy employees are trained on the type of specimen collection. <input type="checkbox"/> Pharmacy has identified a location to collect specimens and has planned the logistics. <i>Specimen collection should take place outside the pharmacy building in an open space to minimize exposure to others.</i> <input type="checkbox"/> Pharmacy has identified a proper method of disposal of specimens and any PPE that may have come in contact with patient.	<input type="checkbox"/> <a href="#">CDC Specimen Collection Guidelines</a> have been reviewed. <input type="checkbox"/> Pharmacy has reviewed the manufacturer's instructions and will follow the instructions completely. <input type="checkbox"/> Pharmacy employees are trained on the type of specimen collection. <input type="checkbox"/> Pharmacy has identified a location to collect specimens and has planned the logistics. <i>Specimen collection should take place outside the pharmacy building in an open space to minimize exposure to others.</i> <input type="checkbox"/> Pharmacy has identified a proper method of disposal of specimens and any PPE that may have come in contact with patient.

Testing Priorities
Both Pathways
<input type="checkbox"/> Pharmacy has a triage system in place and will prioritize testing. <i>Pharmacies should work with local health department to determine local testing needs and should be consistent with <a href="#">CDC</a> and <a href="#">WV DHHR testing priorities</a>.</i>

Communication of Results
Both Pathways
<input type="checkbox"/> <a href="#">CDC Management of Patients with Confirmed COVID-19 Guidelines</a> have been reviewed. <input type="checkbox"/> Pharmacy has a process in place to notify the patient and primary care provider of results. <input type="checkbox"/> Pharmacy has process in place to refer positive patients to their primary care provider and/or physician writing local standing order for COVID-19 testing.

Reporting Results to Local Health Department	
Pathway 1	Pathway 2
<input type="checkbox"/> Pharmacy has confirmed that the laboratory will immediately report all positive results to local health department.	<input type="checkbox"/> Pharmacy has a system in place to immediately report all positive results to local health department.

Reporting Results to WV DHHR	
Pathway 1	Pathway 2
<ul style="list-style-type: none"><li>□ Pharmacy has confirmed that the laboratory will electronically report all results to DHHR in accordance with 64 CSR 7.</li><li>□ If a pharmacy is interested in working with a lab that does not electronically report to WVDHHR, they should have the lab contact the WVDHHR, Division of Infectious Disease Epidemiology at 1-800-423-1271 or 304-558-5358 to learn how to get electronic reporting set up.</li></ul>	<ul style="list-style-type: none"><li>□ Pharmacy will electronically report all results to DHHR in accordance with 64 CSR 7.</li><li>□ The pharmacy must contact the WVDHHR, Division of Infectious Disease Epidemiology at 1-800-423-1271 or 304-558-5358 to learn how to get electronic reporting set up.</li></ul>

List of ELR Reporting Labs as of 5/1/2020

AIT Laboratories
ARUP Laboratories
Beckley Appalachian Regional Hospital
Bioreference Laboratories
Bluefield Regional Medical Center
Boone Memorial Hospital
Cabell Huntington Hospital
Charleston Area Medical Center
Davis & Broaddus/Davis Medical Center
Grafton Hospital
Grant Memorial Hospital
Greenbrier Valley Medical Center
Hampshire Memorial Hospital
Jackson General
LABCORP
Logan (Life Point)
Mako Medical Lab
Marietta Memorial Hospital Lab
Mayo Laboratories
Minnie Hamilton
Mon Health Medical Center
Montgomery General Hospital
Morgan County Hospital
Plateau Medical Center
Pleasant Valley Hospital
Pocahontas Memorial Hospital
Preston Memorial Hospital
Princeton Community Hospital
PWN Health
Quest Teterboro
Quest Pittsburgh
Quest Chantilly
Quest Wood dale
Quest San Juan Capistrano
Quest Atlanta
Quest Dallas
Quest Erie ACL
Quest Horsham

Quest Lenexa
Quest New England
Quest Seattle
Quest Tampa
Quest West Hills
Q Lab
Raleigh (Life Point)
Roane General Hospital
Saint Frances Hospital
Saint Mary's Hospital
Shenandoah Memorial Hospital
Sistersville General Hospital
Stonewall Jackson Memorial
Summers Appalachian Regional Hospital
Sunrise Medical Lab
Thomas Memorial Hospital
Veterans Association Beckley
Veterans Association Huntington
Valley Health System
War Memorial Hospital
Warren Memorial Hospital
Webster County Memorial Hospital
Weirton Medical Hospital
Welch Community Hospital
Wetzel County Hospital
Wheeling Hospital
Winchester Medical Center
WV Office of Laboratory Services
WVU - Berkeley Medical Center
WVU - United Hospital Center
WVU - Ruby
WVU - Summersville Regional
WVU - Jefferson Medical Center
WVU - Camden Clark
WVU - Reynolds Memorial
WVU - Potomac Valley Hospital
WVU - Braxton Hospital
WVU - St Josephs