State of Utah

GARY R HERBERT
Governor

SPENCER J. COX
Lieutenant Governor

Utah Department of Health
Executive Director's Office

Joseph K. Miner, M.D., M.S.P.H., F.A.C.P.M.
Executive Director

Marc E. Babitz, M.D.
Deputy Director

Nate Checketts
Deputy Director
Director, Medicaid and Health Financing

COVID-19 TESTING PROTOCOL
Standing Order for Pharmacists to Administer COVID-19 Tests
Approved June 30, 2020

This Standing Order is issued by Dr. Joseph Miner, Executive Director of the Utah Department of Health (UDOH). Pursuant to the authority provided in Utah Code sections §26-1-30 (3), (5) and(6) and 26-6-3((6), this standing order authorizes a pharmacist licensed under the Pharmacy Practice Act Title 58, Chapter 17b of the Utah Code, to collect SARS-CoV-2 (COVID-19) samples and process COVID-19 tests according to the requirements of this standing order.

On March 10, 2020, the U.S. Department of Health and Human Services (HHS) issued a Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), and on April 8, 2020, the Office of the Assistant Secretary for Health (OASH) issued guidance authorizing licensed pharmacists screen, order, administer, and report results for Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized. Additionally pharmacists may screen, order, and administer non-CLIA waived FDA authorized COVID-19 tests. By doing so, the pharmacists will qualify as "covered persons" under the PREP Act, and they may receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests. See OASH 04/08/2020 Guidance.

This Standing Order authorizes a Utah licensed pharmacist, in accordance with current guidance issued by HHS and OASH and the conditions of this Standing Order, to screen, order, and administer an FDA-approved COVID-19 test to any individual who meets Centers for Disease Control and Prevention (CDC) and/or UDOH guidelines. Based on community demand and available funding, UDOH may authorize a pharmacy to test any individual who requests a test. The pharmacist may also delegate test administration to a Utah licensed pharmacy intern or pharmacy technician, if the delegating pharmacist provides onsite, direct supervision to the delegate.

AUTHORIZED TESTS

A pharmacist, pharmacy intern, or pharmacy technician administering a test shall use an FDA authorized test under emergency use authorization (EUA) listed on the FDA's EUA webpage at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

If the pharmacy is processing the test on site, the pharmacy for which the pharmacist is performing COVID-19 testing shall have the appropriate CLIA waiver/certificate. A CLIA waiver is required for all pharmacies providing CLIA-waived testing.

The FDA has articulated which point of care tests for COVID-19 are CLIA-waived according to an EUA. CLIA-waived tests are listed on the FDA's EUA webpage and indicated by a "W" under the "Authorized Setting(s)" column.

PATIENT ELIGIBILITY

Before a pharmacist, pharmacy intern, or pharmacy technician may conduct a test:

1. The patient shall meet current CDC or UDOH recommendations for testing;

2. The pharmacy shall obtain a signed consent form for each test authorized. The patient, the patient's parent, legal guardian, or other authorized representative reviews and signs a valid consent form. Or, if the patient, patient's parent, legal guardian, or other authorized representative verbally consents to the test, the witness to the verbal authorization signs the consent form. See Appendix A for UDOH's model consent agreement for pharmacies; and

3. The patient (or the patient's parent, legal guardian, or other authorized representative) shall review UDOH's educational material regarding the patient taking self-isolation measures if the COVID-19 test is positive. Instructions for isolation can be viewed, downloaded, and/or printed at https://coronavirus-download.utah.gov/Health/10746_Self-Isolation_Public_Flyer_V6.pdf. A Spanish version is also available: https://coronavirus-download.utah.gov/International-Language-Resources/Spanish/Self-Isolation_Public_Flyer_Spanish_FIN.pdf

PLAN OF CARE

Testing Locations

All testing shall be conducted at a pharmacy or other testing location established by the pharmacy. The pharmacy and the pharmacist administering the test or delegating administration shall ensure that the testing location does not place pharmacy personnel or the public at risk for exposure to active COVID-19 (for example, by providing drive-thru or curbside testing).

Instructions for COVID-19 Diagnostic Testing

A licensed pharmacist, or a licensed pharmacy intern or pharmacy technician under onsite direct supervision by a licensed pharmacist, may collect an appropriate clinical specimen and administer a COVID-19 diagnostic test as follows:

1. The licensee shall follow CDC guidelines for collecting, handling, and testing clinical specimens for COVID-19.

   https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

2. The licensee shall administer the test in accordance with the manufacturer's instructions.

3. The licensee shall activate emergency medical services if a patient appears toxic, is struggling to breathe, or is in serious distress.

Instructions for Point-of-care COVID-19 Antibody Testing:

A licensed pharmacist, or a licensed pharmacy intern or pharmacy technician under on-site direct supervision by a licensed pharmacist, may collect an appropriate clinical specimen for COVID-19 antibody testing as follows:

1. The licensee shall comply with OSHA's Bloodborne Pathogens Standard (29 CFR-1910.1030) in avoiding exposure to bloodborne pathogens and in managing accidental exposure.

2. The licensee shall administer the antibody test in accordance with the manufacturer's instructions.

3. The licensee shall activate emergency medical services if a patient appears toxic, is struggling to breathe, or is in serious distress.

General Recommendations:

Licensees order and administer COVID-19 testing pursuant to HHS authorization to perform the services provided. Licensees shall comply with professional standards of practice.

OSHA's Bloodborne Pathogens Standard (29 CFR-1910.1030) requires a written Exposure Control Plan designed to eliminate or minimize employee exposure.

To ensure patient safety, a pharmacy and all pharmacy personnel take necessary precautions to ensure proper sanitation and prevent unnecessary exposure when testing. Infection prevention and control practices include, but are not limited to:

- Conduct specimen collection and testing outside the physical area of the pharmacy.
    - A pharmacy has a designated area separate and away from regular pharmacy operations for specimen collection and testing.
    - Specimens and potentially contaminated COVID-19 items are not taken outside of the COVID-19 designated testing area.
- Take precautions to ensure patient safety and limit potential exposure to COVID-19 while in the designated specimen collection and testing area.
- Have adequate personal protective equipment (PPE) available and make sure it is used appropriately by pharmacy personnel (including face-shields, respirators or facemasks, gloves, and gowns).
- Have personal protective equipment (face-coverings) available for patients receiving testing and recommend that the patients use them.
- Practice proper hand and glove hygiene, both before and after patient testing.
- Disinfect testing areas routinely and after any potential contamination.

PATIENT FOLLOW-UP

1. Report the test result to the patient; and
2. If a COVID-19 diagnostic test result is positive
    a. Inform the patient they must stay isolated in their home until they have been fever-free, symptoms have gotten better for at least three days, and it has been at least 10 days since they first got sick

b. Inform the patient to expect a call from public health staff to begin contact tracing and encourage the patient to begin a list of their recent close contacts
c. Give the patient any UDOH-developed materials that have been provided to the pharmacy

3. If the patient requests a test result, the lab must provide a report

REPORTING

1. Within 24 hours of test finalization, the pharmacy employing the pharmacist shall report the test result to the Utah Department of Health through the COVID-19 Reporting Portal or electronic laboratory reporting interface.

a. An account for the COVID-19 Reporting Portal can be requested by emailing edx@utah.gov.

b. All test results (positive, negative, equivocal, indeterminate) and required demographic information for both diagnostic and antibody test types shall be reported to the Utah Department of Health according to R386-702 including emergency rule found at https://rules.utah.gov/publicat/bull_pdf/2020/b20200601.pdf.

2. The pharmacist, pharmacy intern or pharmacy technician shall maintain records of all tests administered and test results for two years, including the:

a. patient name;
b. primary care practitioner (if known);
c. test date;
d. name, address, title of administering or delegating pharmacist;
e. name of test;
f. manufacturer; and
g. test results.

Signed by:

Joseph K. Miner, MD

Joseph Miner, M.D., M.S.P.H.

Dated: June 30, 2020

UT Physician/Surgeon License: 161096-1205; UT Prescribing License: 161096-8905

NPI: 1881652980

Expiration Date: This standing order will expire after June 30, 2021.

Appendix A
COVID-19 Informed Consent

Please carefully read and sign the following Informed Consent:

a. I authorize this pharmacy to conduct collection and testing for COVID-19 as ordered by an authorized medical provider or public health official.

b. I understand, as required by law, my test results will be disclosed to the county, state, or to other governmental entity.

c. I understand this pharmacy is not acting as my medical provider, this testing does not replace treatment by my medical provider, and I assume complete and full responsibility to take appropriate action with regards to my test results. I agree I will seek medical advice, care, and treatment from my medical provider if I have questions or concerns, or if my condition worsens.

d. I understand that, as with any medical test, there is the potential for a false positive or false negative COVID-19 test result.

I, the undersigned, have been informed about the test purpose, procedures, possible benefits, and risks. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask additional questions at any time and have been given instructions how to obtain a copy of this Informed Consent. I voluntarily agree to this testing for COVID-19.

Date

First Name Last Name

Signature of Individual or Witness if Verbal Consent Obtained