

MISSOURI BOARD OF PHARMACY

MISSOURI BOARD OF PHARMACY STATEMENT ON COVID-19 TESTING (4-13-20)

The U.S. Department of Health and Human Services (HHS) recently released a [statement authorizing licensed pharmacists to order and administer COVID-19 testing](#). As recognized by HHS, pharmacists have been on the frontline in providing patient care during this unprecedented pandemic. HHS' authorization provides another tool to assist pharmacists in protecting the health and welfare of Missouri citizens. The Board encourages pharmacists to be a part of the solution and is issuing the following guidance to assist Missouri licensees:

GENERAL INFORMATION

To protect patients, pharmacists ordering/administering COVID-19 testing pursuant to HHS' authorization should be appropriately educated/trained to perform the services provided and comply with professional standards of practice. Permit holders should also ensure testing services provided at or on behalf of the pharmacy comply with all applicable law and practice standards. Additionally:

- The Board recommends documenting the patient care services provided. Patients should be referred to their primary care provider for additional treatment/medical care when appropriate.
- Pursuant to [§ 338.035.4](#), intern pharmacists may assist with COVID-19 testing under the direct supervision of a pharmacist.
- COVID-19 testing is a non-dispensing function that can be performed outside of a licensed pharmacy pursuant to [20 CSR 2220-6.055](#). A Board medication therapeutic services (MTS) certificate is not required to order/administer COVID-19 testing pursuant to DHHS' authorization.
- The Board cannot give guidance on specific test selection/requirements, patient screening or payment/reimbursement opportunities. However, review the resource section below for additional CDC recommendations/guidance.

To ensure patient safety, licensees administering testing should take necessary precautions to ensure proper sanitation and prevent unnecessary exposure. Licensees and permit holders should review the CDC's "[Considerations for Pharmacies During the COVID-19 Pandemic](#)" guidance document for cautionary measures to help minimize risk to patients and pharmacy staff. The Board also recommends the following:

- A separately designated patient testing area is recommended to prevent unnecessary exposure and minimize risk for pharmacy personnel and patients. Testing areas should be regularly cleaned and sanitized between patient visits.
- Pharmacy staff should wear personal protective equipment (PPE) when testing. CDC guidance on donning PPE is available online at <https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf>. Pharmacists should be trained on proper garbing technique and evaluated on garbing procedures prior to administering testing.
- In the event of a positive test, permit holders should establish an infection control and response procedure to prevent further risk of exposure (e.g., immediate sanitation/cleaning, quarantining staff or supplies). Appropriate action must be taken to ensure pharmacy safety and sanitation.

*****SEE THE ATTACHED DHSS STATEMENT ON REPORTING POSITIVE RESULTS*****



ADDITIONAL FEDERAL REQUIREMENTS

Licensees should consult with legal counsel to ensure compliance with applicable state and federal laws, including, the [Clinical Laboratory Improvement Amendments of 1988](#) (CLIA). At this time, the federal government has not waived [CLIA](#) requirements.

- **CLIA-Waived Testing:** The Board has been advised by the Missouri Department of Health and Senior Services (DHSS) that a CLIA certificate is required for pharmacies providing diagnostic testing. DHSS administers the CLIA program in the state of Missouri. Information on applying for a CLIA certificate is available on DHSS' website at <https://health.mo.gov/safety/clia/>. The Missouri CLIA Program can also be contacted at: CLIA@health.mo.gov or by telephone at 573-751-6318. Only waived testing is allowed with a CLIA certificate of waiver.

The FDA is continuously reviewing and approving new COVID-19 testing kits. Please refer to the FDA website for COVID 19 approved tests and complexity. The FDA is continuously making updates and changes. A link to the FDA EUA approved tests can be found here: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

Questions regarding CLIA certification applications/requirements should be addressed to DHSS/CLIA. The Board of Pharmacy cannot answer CLIA questions.

- **Non-Waived CLIA Testing:** For non-waived CLIA testing (moderate and high complexity testing), a CLIA compliance certificate is required. DHSS/CLIA will expedite all applications, but regulatory standards will be applicable. Questions regarding non-waived CLIA testing should also be addressed to the Missouri CLIA Program at the e-mail address/phone number listed above.

ADDITIONAL RESOURCES

The following CDC resources are recommended:

1. [Considerations for Pharmacies during the COVID-19 Pandemic](#)
2. [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons with Coronavirus Disease 2019 \(COVID-19\)](#)
3. [Evaluating and Testing Persons for Coronavirus Disease 2019 \(COVID-19\): https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html](#)
4. [PPE Recommendations](#)
5. [CDC Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 \(COVID-19\) in Healthcare Settings](#)





Missouri Department of Health and Senior Services

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RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director



Michael L. Parson
Governor

Date March 24, 2020

Regarding: Mandatory Reporting for all MO medical facilities/laboratories providing testing for COVID-19:

Please be advised that it is now required by Executive Order for facilities in Missouri to report all positive and negative results for COVID-19 only to the Missouri Department of Health and Senior Services. See link below: (<https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/reporting-of-covid-19-lab-results.pdf>).

The following technical guidance is provided to assist laboratories and providers in meeting this requirement.

Laboratories:

- Laboratories reporting through electronic laboratory reporting prior to March 20, 2020, can continue to provide results through that method.
- Other laboratories may provide results electronically by submitting Excel line listings via the state's secure file transfer protocol (SFTP) site. Laboratories may request access to the SFTP site by contacting Becca Mickels with the Bureau of Reportable Disease Informatics at Becca.Mickels@health.mo.gov or Angela McKee at Angela.McKee@health.mo.gov.
- Laboratories unable to provide COVID-19 results electronically may fax results to 573-751-6417.

Hospitals and Other Medical Providers:

- Per 19 CSR 20-20.020, both laboratories and hospitals are required to report. Due to the expected volume of negative test results, ***hospitals that are working with a separate commercial laboratory that is reporting do not need to submit negative laboratory results.***
- Hospital laboratories need to submit all results as required for other laboratories above.
- Hospitals and other providers must submit case reports on positive and indeterminate cases.

Please let me know if you have questions regarding reporting.

Thank you,

Becca Mickels, Chief
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Sent via MO CLIA Program
Bureau of Diagnostic Services
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