

## **Division of Public and Behavioral Health**

## **Technical Bulletin**



**Topic:** Pharmacists & Medical Laboratory Testing Under the PREP Act

Contact: Bureau of Health Care Quality and Compliance/Phone: 775-684-1030

Date: June 2, 2020 To: Pharmacists

Under the Public Readiness and Emergency Preparedness (PREP) Act, the federal government has authorized pharmacists to order and perform viral and serology testing for COVID-19 and has pre-empted state law requirements including a Nevada medical laboratory license as described in Chapter 652 of the Nevada Revised Statutes. According to the Centers for Medicare and Medicaid Services (CMS), a pharmacist must still obtain a Clinical Laboratory Improvement Amendments (CLIA) certification appropriate for the type of testing they are performing PRIOR to performing any tests.

Steps for pharmacists to begin medical laboratory testing include:

1) All pharmacists are required to obtain their CLIA certification by completing and submitting the Clinical Laboratory Improvement Amendments (CLIA) Forms found here:

http://dpbh.nv.gov/Reg/MedicalLabs/dta/Forms/Medical\_Laboratories - Forms/ The CLIA forms must be submitted via one of the following options:

Via Mail:

Division of Public and Behavioral Health – Bureau of Health Care Quality and Compliance Medical Laboratory Services Unit 727 Fairview Drive, Suite E Carson City, NV 89701

Via Fax: 775-684-1073

Via email: <a href="mailto:pbhmedlabs@health.nv.gov">pbhmedlabs@health.nv.gov</a>

- 2) All pharmacists are encouraged (although not required) to report COVID-19 test results by following the instructions noted below.
  - 1.) Go to the following website: http://dpbh.nv.gov/Programs/OPHIE/Public\_Health\_Informatics\_and\_Epidemiology\_-\_Home/
  - 2.) Click on "Confidential Disease Reporting Form." Fill out the first page and print. The second page contains instructions on completing the form if needed. Fax the form to: 702-759-1454.
  - 3.) Please note that all results of confirmed cases and/or for suspect cases that are still awaiting confirmation, must be reported immediately
- 3) Although not required, the Division of Public and Behavioral health will assist any pharmacist who wants to become a Nevada licensed medical laboratory. For more information on medical laboratory licensing, go to the Division of Public and Behavioral Health's website at: http://dpbh.nv.gov/Reg/MedicalLabs/Medical\_Laboratories - Home/

COVID-19 viral testing expansion is urgently required to determine the impact of asymptomatic cases on viral spread. Asymptomatic, subclinical and pre-symptomatic COVID-19 infections might contribute to the ongoing viral transmission. Current symptom-based screening strategies seem to be inadequate to identify or early detect all COVID-19 cases to prevent viral spread in the community and the transmission of infection within skilled nursing homes and other residential facilities.

COVID-19 data and test results that include those who don't show symptoms can provide a more accurate understanding of how the virus is spreading in the community. Such critical findings will inform future policies and guidelines. Identifying asymptomatic cases will provide a better understanding of the virus's impacts on the community. Expansion in viral testing will play a major part in influencing the state's continuous adjustment of prevention, community mitigation and control measures. This additional testing expansion may also lead to a larger number of residents made aware of their conditions, knowledge that could contribute to focused social distancing and further slowing community transmissions. Proceeding timely, cautiously, carefully and incrementally with testing, tracing and containment enhances our attainments and helps avoid setbacks.

Health care providers are going to make decisions for treatment and/or diagnosis of their patients based upon the test results that they receive. Inaccurate test results may cause a misdiagnosis or improper treatment of the patient. In addition, a lab result given to the individual could dictate his or her future actions. A positive COVID-19 antibody test may lead a person to believe that they have the antibody and will feel they are protected. Some of the COVID-19 tests are not specific for the COVID-19 antibody: the test can be positive but indicate that the person has been introduced to a coronavirus but not necessarily the COVID-19 virus.

Medical laboratory oversight through licensure helps navigate through the different issues that may be encountered when choosing tests to perform and helps to ensure tests are properly validated to ensure accurate testing. The Nevada Department of Health and Human Services recognizes that both medical laboratory licensure and reporting of COVID-19 test results will help ensure pharmacists are providing accurate test results; may increase public confidence in using pharmacists for medical laboratory testing; and lead to better protection of public health by reporting COVID-19 test results to state and local health authorities.

Signed: \_\_\_\_\_ Date: 6/2/2020

Lisa Sherych Administrator

Signed: Date: 6/2/2020

Ihsan Azzam, PhD, MD Chief Medical Officer