

Steve Sisolak
Governor



Richard Whitley, MS
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
Helping people. It's who we are and what we do.



Lisa Sherych
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical Officer

March 11, 2022

Mohindra Meena, Owner
Northshore Clinical Laboratories, LLC
4751 North Kedzie Avenue
Chicago, IL 60625-4420

Email: omar@northshoreclinical.com

Dear Mohindra Meena,

The Nevada Division of Public and Behavioral Health (Division) has concluded its Complaint Investigation of the Las Vegas, Nevada (NV) laboratory owned and operated by Northshore Clinical Laboratories, LLC. The Division substantiated deficient practices in violation of Nevada Revised Statutes (NRS) Chapter 652, as documented through the Statement of Deficiencies provided on January 31, 2022. The Division has accepted the plan of correction submitted on February 14, 2022. As stated in the plan of correction, and in accordance with conversations between the Division and Northshore Clinical Laboratories, LLC, your organization will no longer continue operating in the State of Nevada. However, because Northshore Clinical Laboratories, LLC provides services in other areas, the following is provided for informational purposes to assist with the accuracy of lab results in the rest of the country or in future operations.

Timeline of the investigation:

An initial complaint was submitted to our State Agency on January 14, 2022, against the Northshore Exempt Laboratory located in Las Vegas, Nevada (NV) alleging that the laboratory was performing PCR COVID-19 testing without a license.

The laboratory had been approved to perform COVID-19 Antigen testing for this location but was found to also be reporting results of PCR COVID-19 PCR testing. During the complaint investigation, it was discovered that no PCR COVID-19 testing was being performed in Nevada, but it was found that the PCR COVID-19 testing that was being reported, was being performed only in the Northshore Clinical Laboratory in Chicago, IL. In addition, it was discovered that COVID-19 Antigen testing and COVID-19 specimen collection being sent to the Northshore Clinical Laboratory Chicago location for PCR COVID-19 testing was being performed in a Washoe County, NV, location that was not licensed to perform such services in violation of Nevada Medical Laboratory statutes and regulations.

Of concern, a representative from the Nevada State Public Health Laboratory (NSPHL) noted that the methodology that Northshore Clinical Laboratory was using for PCR COVID-19 testing had resulted in a 96.1%

false Negative rate of patient COVID-19 test results. Northshore suspended PCR COVID-19 testing for Washoe County, Nevada while Northshore was investigating the problem.

A complaint investigation of the Northshore Exempt Laboratory in Las Vegas found seven deficient laboratory practices in which the laboratory director failed to:

- 1) Ensure that training and competency assessments of all testing personnel was completed in order to ensure the accuracy of laboratory test results.
- 2) Ensure that laboratory tests were performed in accordance with the manufacturer's instructions.
- 3) Ensure that external quality controls were performed according to the manufacturer's requirement for External Quality Control used to determine if patient testing may be performed.
- 4) Ensure the health, welfare, and safety of the personnel of the laboratory by not providing a safe environment in which employees are protected from biological, chemical, and physical hazards.
- 5) Ensure that certification pursuant to NAC 652.470 was obtained for the Medical Assistants and Laboratory Assistants and pay the applicable fees as set forth in NAC 652.488.
- 6) Ensure that patient samples were not tested prior to approval by the Division.
- 7) Report the findings or results of laboratory tests; actively participate in the operation of the laboratory to the extent necessary to assure compliance with the provisions of this chapter, be responsible for the proper performance of all work in the laboratory and of all subordinates and retain regularly maintained records of the laboratory in accordance with regulations adopted by the Board pursuant to NRS 652.135.

A Statement of Deficiencies (SOD) was sent to your laboratory on January 31, 2022, for your laboratory to respond with an acceptable Plan of Correction (POC) within 14 days.

On February 14, 2022, your laboratory submitted a Plan of Correction to our agency. An email was sent to Northshore on February 22, 2022, to inform you of the unacceptable submission and also to communicate the revisions needed for the POC to be acceptable.

On February 23, 2022, Northshore notified the Division that it was discontinuing COVID-19 Antigen testing and COVID-19 specimen collection in Nevada.

On March 2, 2022, our agency received a letter from Northshore voluntarily requesting to close the State of Nevada laboratory license and the federal CLIA certificate. On March 3, 2022, a revised POC was received, including more than 600 pages of supporting documentation. The complaint investigation packet was completed. Had your organization been continuing services in Nevada, additional follow up would have been required, however considering the discontinuation of services, additional follow up was not required.

On March 4, 2022, the complaint investigator did a follow-up onsite visit to the laboratory address in Las Vegas, NV to ensure the laboratory had closed and found that the laboratory had not secured protected patient information such as patient test results. A voicemail was left with Northshore notifying them that patient information was available in an unsecured area in violation of federal HIPAA requirements. On March 7, 2022, Division staff went onsite and confirmed that the patient reports had been collected and the door had been secured, as reported by Northshore.

I sincerely hope that you will use this information to ensure improved business practices across your organization. If you have questions or concerns, please reach out to the Division, Bureau of Health Care Quality and Compliance at 775-684-4200.

Sincerely,



Cody L. Phinney
Deputy Administrator
Department of Health and Human Services
Division of Public and Behavioral Health

CC by email:

Brad Waples, Manager Medical Labs, BHCQC
Paul Shubert, Bureau Chief, BHCQC
Lisa Sherych, Administrator, DPBH
Josh Cohen, CMS, DCIQ
Richard Whitley, Director DHHS