

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2215525	(X3) Date Survey Completed 05/24/2022
Name of Provider or Supplier Mdx Labs Llc	Street Address, City, State 8 Sunset Way Ste 101, Henderson, NV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility on May 24, 2022. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the director approved policy entitled, "Daily Temperature Checks," a review of the laboratory temperature logs, and an interview with the laboratory director and technical supervisor, the laboratory failed ensure that corrective action was taken for refrigerator temperatures that exceeded the acceptable ranges established by the laboratory. Findings include: 1. The director approved policy entitled, "Daily Temperature Checks" stated, "Any temperature and/or humidity measurements that exceed the recommended temperature/humidity ranges must be corrected before testing can proceed." 2. A review of the laboratory logs entitled, "Daily Temperature and Humidity Log--Prep Room" revealed that the current refrigerator temperatures exceeded the acceptable ranges on 110 of 250 days between the dates of April 15, 2021 and January 31, 2022 with no documentation of corrective action, until August 28, 2021, and February 22, 2022. 3. A review of the laboratory logs entitled, "Daily Temperature and Humidity Log--Prep Room" revealed that the minimum refrigerator temperatures exceeded the acceptable ranges on 149 of 250 days between the dates of April 15, 2021 and January 31, 2022 with no documentation</p>

of corrective action, until August 28, 2021, and February 22, 2022. 4. A review of the laboratory logs entitled, "Daily Temperature and Humidity Log--Prep Room" revealed that the maximum refrigerator temperatures exceeded the acceptable ranges on 167 of 250 days between the dates of April 15, 2021 and January 31, 2022 with no documentation of corrective action, until August 28, 2021, and February 22, 2022. 5. The findings were confirmed during an interview with the laboratory director, and the laboratory manager on May 24, 2022 at approximately 11:30 AM. The laboratory performs approximately 30,000 Virology tests annually.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on a review the laboratory quality assessment records, and an interview with the laboratory director and the laboratory manager, the laboratory director failed to ensure that quality assessment was performed and documented according to the established program to detect and correct failures in quality when they occur. Findings include: 1. There was no documentation of quality assessment activities between the dates of April, 2021 and December, 2021. 2. The findings were confirmed during an interview with the laboratory director and the laboratory manager on May 24, 2022 at approximately 10:45 AM. The laboratory performs approximately 30,000 Virology tests annually.