

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2209971	(X3) Date Survey Completed 06/30/2022
Name of Provider or Supplier Neelyx Labs	Street Address, City, State 330 Georgetown Square, Wood Dale, IL	
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
D6168	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to employ three of eleven individuals who meet the education qualification requirements to perform the procedures and analysis of Real-Time Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) testing (D6171) in the subspecialty of Virology prior to testing patients.</p>
D6171	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or</p>

medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure three of eleven employees meet the education qualification requirements to perform Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures, affecting 110,713 patients' tests. Findings: 1. The Laboratory Personnel Report (CMS 209), the Clinical Laboratory Improvement Amendments (CLIA) application (CMS-116), and testing personnel (TP) files were reviewed. 2. The CMS 209 identified employees K4, J5 and B9 as testing personnel (TP) performing RT-PCR procedures to detect and identify the SARS-CoV-2 virus. 3. The employee files of K4, J5, and B9 revealed the following: *K4 and B9 received training and competency in January and February of 2021 and B9 received training and competency in April 2022. *K4 and J5 foreign credentials failed to include the course by course United States equivalency evaluation. *The transcript of B9 documented that they had received a Bachelors of

Art in Anthropology/Creative Writing and minor in Museum Studies. 4. The laboratory failed to ensure three of eleven TP meet the education requirements as defined in 493.1489 prior to testing patients. 5. The laboratory reported 110,713 patients' tests annually. 6. The owner and Staff #2 on June 30, 2022 at 3:50 PM confirmed the above findings.