

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2209971	(X3) Date Survey Completed 10/21/2025
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Proficiency Institute (API) proficiency testing (PT) records, laboratory records, lack of documentation, and interview with technical supervisor (TS) #2; the laboratory failed to ensure accuracy of ten of ten PT samples not evaluated by the PT provider in the subspecialties of routine chemistry, virology, and syphilis serology in 2024 and 2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Proficiency Testing Policy", which stated, under "3. Definitions", "Unsuccessful participation or unsuccessful performance in proficiency testing: An unsatisfactory testing event score for those subspecialties not graded by analyte" and, under "5. Policy", "If the results are unacceptable to unsatisfactory, an investigation should be initiated to determine the cause of the failure." 2. Review of API comparative evaluation summaries for the following PT events of 2024 and 2025 revealed the following ungraded PT samples: PT Event: PT sample: Sample: 2024 Event 1 Bilirubin, total CH-02 2025 Event 1 Syphilis Ab* screen SYP-01 2025 Event 1 Syphilis Ab screen SYP-04 2025 Event 1 HSV** - type 2 STI-02 2025 Event 2 Alkaline phosphatase CH-06 2025 Event 2 Bilirubin, total CH-07 2025 Event 2 Bilirubin, total CH-09 2025 Event 2 Bilirubin, total CH-10 2025 Event 3 Bilirubin, total CH-12 2025 Event 3 Bilirubin, total CH-15 *Ab = antibody **HSV = Herpes Simplex Virus 3. Review of laboratory records found no documented review of the ungraded PT samples in the subspecialties of routine chemistry, virology, and syphilis serology in 2024 and 2025. 4. Interview with TS #2 on 10/21/2025, at 2:32 pm, confirmed the laboratory failed to ensure accuracy of ten of ten PT samples not evaluated by the PT provider in 2024 and 2025.</p>