

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2018484	(X3) Date Survey Completed 01/25/2023
Name of Provider or Supplier Una Sibirceva Md Pc	Street Address, City, State 2769 Coney Island Ste 3r, Brooklyn, NY	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) records 2021 and 2022, the pain management test list and confirmed in an interview with the technical/general supervisor/testing personnel, the laboratory failed to evaluate and verify the accuracy of 53 out of 53 toxicology analytes in the years 2021 and 2022. FINDINGS: 1. The laboratory performed API PT Urine Drug Screening (UDS) testing for the two adulterants: pH & specific gravity, and five analytes: Oxycodone, Opiates, Methadone, Cocaine, and Acetylmorphine(6-AM), performed on the Carolina Bolis 24i 480 analyzer for the calendar year 2021 and discontinued screening testing on the analyzer 1/2022. 2. The laboratory failed to verify 53 out of 53 confirmatory testing performed on the Aligent AB Sciex mass spectrometry (LC/MS/MS) for the calendar years 2021 and 2022. 3. Approximately 1500 patients specimens were tested during calendar years 2021 and 2022. 4. The technical/general supervisor/testing personnel, confirmed on January 25, 2023, at approximately 2:00 P.M., that the laboratory failed to verify the accuracy of 53 out of 53 toxicology analytes in the calendar years 2021 and 2022. a. The laboratory is enrolled in 2023 College of American Pathologists (CAP) Drug Monitoring Pain Management (DMPM) for twice year verification for 53 analytes.</p>