

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2018484	(X3) Date Survey Completed 04/23/2025
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 Standard Operating Procedures (SOPs), CAP Drug Monitoring for Pain Management (DMPM) records, CAP DMPM test menu, as well as interview with the Technical Consultant (TC), the laboratory failed to successfully participate in a toxicology specialty PT program for three analytes. FINDINGS: 1. There was no documentation of Phencyclidine, Ritalinic Acid, and Tricyclic Antidepressants (TCAs) PT performance or twice year verification for 2023 and 2024. 2. This is contrary to instructions indicted in the current, approved SOPs. 3. It was noted that quality control and assessment was performed for the respective analytes. 4. Approximately 333 patients were tested for the respective analytes in 2023 and 2024. 5. The TC confirmed the findings on April 23, 2025, at 12:00 P.M.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of SOPs, lack of PT documentation, as well as interview with the TC, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory services. Refer to D5217.</p>