

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1068412	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier Neal S Taub, Md, Pa	Street Address, City, State 3535 Randolph Road, Suite 208, Charlotte, NC	
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 upon review of 2022 and 2023 API (American Proficiency Institute) PT (proficiency testing) records, review of the laboratory's test menu, review of data to verify performance specifications and interview with TP#1 (Testing Personnel) on 2/15/24, the laboratory failed to verify the accuracy of 1 of 8 analytes performed on the Viva-E instrument twice annually. Findings: Review of 2022 and 2023 API-PT records confirmed the laboratory's enrollment of the following urine analytes: 1. Amphetamine/Methamphetamine 2. Benzodiazepines 3. Buprenorphine 4. Cannabinoids 5. Cocaine Metabolites 6. Methadone 7. Opiates Review of the laboratory's test menu revealed that the laboratory also performs testing for urine oxycodone. Review of data to verify the performance specifications of urine oxycodone revealed the laboratory implemented this analyte in October 2022. In interview at approximately 9:45 a.m., TP#1 confirmed the following: 1. The laboratory has not enrolled urine oxycodone into API-PT. 2. The laboratory does not assess the accuracy of urine oxycodone in any manner twice annually.</p>
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p>

This STANDARD is not met as evidenced by:

Based upon review of the Viva-E Reference Guide, review of 2022 and 2023 Viva-E maintenance logs and interview with TP#1 (Testing Personnel) on 2/15/24, TP#1 failed to document the performance of all Viva-E instrument maintenance. Findings: Review of the Viva-E Reference Guide revealed a Maintenance section that detailed required maintenance at the following time intervals: 1. Daily 2. Weekly 3. Monthly 4. Quarterly Review of 2022 and 2023 Viva-E maintenance logs revealed the documentation of daily and weekly tasks. In interview at approximately 10:05 a.m., TP#1 confirmed the following: 1. He performs all maintenance tasks. 2. He does not document monthly and quarterly maintenance tasks.