

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2226770	(X3) Date Survey Completed 02/10/2022
Name of Provider or Supplier Technical Resource Management, Llc	Street Address, City, State 5604 Fortune Circle South, Suite N, Indianapolis, IN	
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 record review and interview, the laboratory failed to biannually verify the accuracy of its testing for five of 20 analytes (methamphetamine, tramadol, barbiturates, ethanol, and methylenedioxymethamphetamine (MDMA)) tested in oral fluid using the Olympus Chemistry Analyzer AU5400 Series (serial number 6061179) in the specialty of Chemistry from August 31, 2021 to February 10, 2022. Additionally, the laboratory failed to biannually verify the accuracy of its testing for 11 of 20 analytes (methamphetamine, tramadol, barbiturates, ethanol, ethylglucuronide (ETG), propoxyphene, gabapentin, MDMA, pH, creatinine, and specific gravity (SpGR)) tested in urine using the Olympus Chemistry Analyzer AU640 (serial number 9030181), and the Olympus Chemistry Analyzer AU2700 (serial number 8041545) in the specialty of Chemistry from August 31, 2021 to February 10, 2022. Findings include: 1. Oral Fluid: A. Review of the College of American Pathologists (CAP) proficiency testing (PT) evaluation of the "Oral Fluid for Drugs of Abuse" kit, dated 1/6/2022, as well as its corresponding "Oral Fluid for Drugs of Abuse Result Form", dated 12/21/2021, indicated: 1) Tramadol, barbiturates, and ethanol were not included in the 1/6/2022 proficiency testing submission. 2) The laboratory documented to CAP on the "Oral Fluid for Drugs of Abuse Result Form" that MDMA and methamphetamine were normally referred to a reference laboratory, so no MDMA or methamphetamine results were provided to be evaluated. B. On 02/10/2022 at 10:35 am, SP1 indicated that only positive results are referred to the reference laboratory for quantitation. C. On 02/10/2022 at 1:45 pm, SP1 confirmed that the evaluation and the "Oral Fluid for Drugs of Abuse Result Form" was the only proficiency testing submission completed by the lab. D. On 02/10/2022 at 1:52 pm,</p>

SP1 acknowledged that an approved proficiency testing program had not evaluated oral fluid testing results for methamphetamine, tramadol, barbiturates, ethanol, and MDMA. E. On 02/10/2022 at 2:00 pm, SP1 indicated that the laboratory had not verified the accuracy of oral fluid testing results for methamphetamine, tramadol, barbiturates, ethanol, and MDMA. 2. Urine: A. On 02/10/2022 at 11:52 am, SP1 indicated that the Olympus Chemistry Analyzer AU5400 Series tests oral fluid and that the Olympus Chemistry Analyzer AU640 and the Olympus Chemistry Analyzer AU2700 tests urine. B. On 02/10/2022 at 1:45 pm, SP1 indicated that the lab enrolled in proficiency testing using oral fluid, and not urine. C. On 02/10/2022 at 2:00 pm, SP1 indicated that the lab had not verified the accuracy of urine testing results for methamphetamine, tramadol, barbiturates, ethanol, ETG, propoxyphene, gabapentin, MDMA, pH, creatinine, and SpGR. 3. Annual test volume for oral fluid tests of methamphetamine, tramadol, barbiturates, ethanol, and MDMA and urine tests of methamphetamine, tramadol, barbiturates, ethanol, ETG, propoxyphene, gabapentin, MDMA, pH, creatinine, and SpGR is approximately 125,548.