

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D2004621	<b>(X3) Date Survey Completed</b> 03/05/2024
<b>Name of Provider or Supplier</b> Opans, Llc	<b>Street Address, City, State</b> 4134 Alston Avenue, Suite 100, Durham, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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 CAP-PT(College of American Pathologists)-(Proficiency Testing) records and interview with the LD(Laboratory Director) on 3/5/24, the laboratory did not assess the accuracy of 27 of 85 urine toxicology analytes twice annually. Findings: Review of 2022 and 2023 CAP-PT records revealed the following: 1. The laboratory is enrolled in the CAP DMPM (Drug Monitoring for Pain Management) module. 2. The DMPM module contains 27 of the 85 urine toxicology analytes performed in the laboratory. In interview at approximately 11:30 a.m., the LD confirmed the laboratory's CAP enrollment is the only activity performed to verify the accuracy of urine toxicology analytes.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p>

Based upon review of the laboratory's policy, review of 2022, 2023 and 2024 laboratory records and interview with TP#2 (Testing Personnel) on 3/5/24, the laboratory failed to document its incubator temperature each day of patient testing. Findings: Review of the laboratory's Analytical Test Method policy revealed in Section: "Specimen, QC and Analytical Standards Preparation: Plate preparation: Step 6. Mix gently and heat at 60 degrees Celsius for approximately 30 minutes." Review of 2022, 2023 and 2024 laboratory records revealed the absence of documentation of the incubator temperature each day of patient testing. In interview at approximately 2:15 p.m., TP#2 confirmed that he does not document the incubator's temperature.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based upon review of two patient test reports (1284494 and 1319094) and interview with the Laboratory Director on 3/5/24, the laboratory does not disclose the cut off values of 30 drug classes included in their dried blood and urine toxicology screening profiles. Findings: Review of two patient test reports (1284494 and 1319094) revealed the absence of cut off values for 30 drug classes contained in the dried blood and urine toxicology screening profiles. In interview at approximately 3:30 p.m., the Laboratory Director confirmed the findings.