

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2155295	<b>(X3) Date Survey Completed</b>  02/14/2024
<b>Name of Provider or Supplier</b>  Gmi Laboratories, Llc	<b>Street Address, City, State</b>  1278 E Colorado Blvd, Pasadena, CA	
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>D2109</b>	<p><b>TOXICOLOGY</b> CFR(s): 493.845(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of second quarter event in 2022 (Q2-2022)) of the College of American Pathologist (CAP) proficiency testing (PT) records, random patient sampling test results, and interview with the laboratory director (LD) and technical supervisors (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in the Urine Toxicology Identification The findings included: 1. The CAP reported for Q2-2022, an unsatisfactory PT score of 25%. 2. The LD and TS affirmed on February 14, 2023, at approximately 10:50 a.m. that the laboratory received the above unsatisfactory proficiency test scores stated in 1. 3. Based on the test volume declaration signed by the laboratory director on 2/14/2024 the laboratory tested and reported 5,000 Toxicology urine sample confirmation tests.</p>
<b>D6091</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: The laboratory director is cited herein for failing to ensure all proficiency testing reports received identify any problems that require corrective action, such as review</p>

of quality control, calibration, and preventive maintenance records on the day the testing was performed. See D 2109.