

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2007334	(X3) Date Survey Completed 03/21/2025
Name of Provider or Supplier Tlc Laboratory	Street Address, City, State 13422 Newport Ave, Suite L, Tustin, CA	
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(a) 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 interview with Technical Supervisor (TS), review of Proficiency Testing (PT) evaluation records and review of ten (10) randomly chosen patients records on March 17, 2025, it was determined that the Laboratory failed to attain a score of at least 80% of acceptable responses for Chloride in the second event of 2024, which was unsatisfactory analyte performance for the testing event. The findings include: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for Chloride testing using Horiba Medical Pentra 400 instrument in 2023, 2024 and 2025. According to the API evaluation, the laboratory attained a score of 40% in the second event of 2024 for Chloride as follow: Event /Analyte Sample Repored Expected Result Result Q2 2024 Chloride CH-06 103 106-118 Q2 2024 Chloride CH-08 80 81-90 Q2 2024 Chloride CH-10 83 84-94 2. On March 17, 2025, at approximately 12:00 pm the Technical Supervisor affirmed that the laboratory received the above unsatisfactory proficiency scores. 3. The laboratory's testing declaration form, signed by the laboratory director on March 13, 2025, stated that the laboratory performed approximately 7000 Routine Chemistry tests including Chloride annually.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing reports and interview with the technical supervisor on March 17, 2025, the laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. See D2087