

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2007334	(X3) Date Survey Completed 05/19/2021
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
D2099	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with laboratory technical personnel (TP) on 5/19/21 between 1:00 p.m. and 3:00 p.m., it was determined that there were several unacceptable (below 80 %) proficiency testing (PT) results for Thyroid Stimulating Hormone (TSH) for Cycle 1 in the testing year 2019. Findings include: 1. On 5/19/21, an inspection was conducted between 1:00 p.m. and 3:00 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 2:30 p.m. that there were several unacceptable PT results for cycle Q1 TSH on the 2019 report. The laboratory utilizes the Horiba Pentra 400 instrument for general chemistry testing The TP recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: TSH (3/5 Unacceptable) Sample Actual Result Expected Result (range) CH03 5.79 3.86-5.34 CH04 0.50 0.34-0.46 CH05 3.25 2.14-2.88 4. The TC affirmed the unacceptable results listed above.</p>
D6007	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</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 test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the</p>

tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on a review of the proficiency laboratory documentation records and interviews with the LP, it was determined that the laboratory director failed to ensure the verification and accuracy of test results of regulated analytes and to identify failures as they occurred for the previously mentioned Cycle 1 2019 proficiency testing. The findings include: See D-2099