

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2007334	(X3) Date Survey Completed 01/25/2019
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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient testing and quality control records, lack of corrective actions records, and interview with the laboratory personnel, the laboratory failed to take any corrective action when the results of control failed to meet the laboratory's criteria for acceptability. The laboratory also, failed to evaluate to determine if patient test results have been adversely affected since the last acceptable test run. The findings include: a. The laboratory's quality control record shows that its high CBC QC failed 4 consecutive runs on 1/25/2019 at 13:13, 13:16, 13:22 and 13:25. The laboratory did not have any document showing that any corrective action was taken for the above control failure. b. On January 25, 2019 at 2:47 pm laboratory testing personnel affirmed that the laboratory did not take any corrective action and have no records. c. The laboratory's testing declaration form, signed by the laboratory Director on January 19, 2019, stated that the laboratory performs 1,623 tests annually.</p>
D6024	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on Surveyor review of patient testing and quality control records, laboratory's policy & procedure, lack of corrective action records and documentation, and interview with the laboratory personnel, the laboratory Director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified. The findings include: See D5783