

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2040304	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier Md Tox Laboratory	Street Address, City, State 1565 McGaw Ave Ste B, Irvine, 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
D5217	<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 on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory's personnel, it was determined that the laboratory failed to verify, at least twice annually, the accuracy of any test or procedure it performed which are not listed in subpart I of 42 CFR part 493. The findings included: a. The laboratory failed to verify and ensure, at least twice annually, the accuracy of the test procedures it performed, which are not listed in the subpart I of 42 CFR part 493. b. The laboratory performed routine chemistry and general immunology including, but are not limited to the following test procedures of CA-125, Folate, TIBC and Urine Creatinine, which are not listed in the subpart I of 42 CFR part 493. c. The laboratory enrolled with American Proficiency Institute (API) PT programs to verify and ensure the accuracy of the test procedures it performed. d. The laboratory failed to attain scores of at least 80% for the following analyte in the API PT events: Score in %; U = Urine; Vol = estimated monthly patient test volume. PT event Analyte Score Vol Q2 2022 CA 125 50 60 Q2 2022 Folate 50 100 Q1 2022 TIBC 60 42 Q2 2021 U Creatinine 33 2 Q1 2022 U Creatinine 0 2 e. The laboratory personnel affirmed (4/19 /2023 @ 12:40 PM) that the laboratory failed to verify and ensure the accuracy of the tests for the listed on (c) above.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required and failed to attain scores of at least 80% to verify and ensure the accuracy of test procedures. The findings included: a. The laboratory director failed to ensure the accuracy of API PT samples that the laboratory performed and attained scores of at least 80% for the analyte of CA-125, Folate, TIBC and Urine Creatinine, see D-5217