

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2040304	(X3) Date Survey Completed 05/28/2025
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
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 review of the American Proficiency Institute (API) proficiency testing records, and interview with the Technical Supervisor (TS), the Technical Supervisor (TS), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Routine Chemistry analytes Bilirubin and Lactate Dehydrogenase (LDH). The finding included: 1.The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for routine chemistry testing using Beckman Coulter AU680 instrument. According to the API evaluation, the laboratory attained the following unsatisfactory scores: Q3- 2023: Bilirubin= 0% Q1- 2025: LD/LDH= 0% 2. On May 28th, 2025, at approximately 11: 30 am 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 May 15, 2025, stated that the laboratory performed approximately 1,179 Lactate Dehydrogenase (LDH) tests and 9,246 Bilirubin tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(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>

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the Technical Supervisor (TS), the Technical Supervisor (TS), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Endocrinology analytes Prolactin and Thyroxine (T4). The finding included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for endocrinology testing using Beckman Unicel Dxi 800 instrument. According to the API evaluation, the laboratory attained the following unsatisfactory scores: Q3- 2024: Prolactin= 0% Q1- 2025: T4= 60% 2. On May 28th, 2025, at approximately 11:30 am 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 May 15, 2025, stated that the laboratory performed approximately 4,186 Prolactin tests and 37,553 T4 tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures manuals, laboratory records and interview with the Technical Supervisor (TS) on May 28th, 2025, at approximately 2:00 pm, the laboratory failed to review monthly quality management summary to verify that the laboratory has a system in place to ensure continuous improvement. The findings include: 1. It was practice of the laboratory to perform routine chemistry, urinalysis and toxicology testing using Beckman Coulter AU680 instrument. 2. On May 28th, 2025, at approximately 2:00 pm, the Technical Supervisor (TS) affirmed the laboratory did not review monthly quality management summary for all tests perform using AU680 analyzer. 3. The laboratory's testing declaration form, signed by the laboratory director on May 15, 2025, stated that the laboratory performed approximately 425,860 tests using AU680 analyzer annually.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, 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 interview with Laboratory Director (LD) and Technical Consultant (TC), review of Proficiency Testing and Quality Assessment records on May 28th, 2025, the laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings included: 1-The LD failed to ensure the proficiency testing samples were tested as required under subpart H of 42 CFR 493. See D2087, D2098 2- The LD failed to ensure that quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5791

D6080

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(c)

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's records and interview with the laboratory Director (LD) and Technical Supervisor (TS), the laboratory director failed to determine any specific type or process of documentation required as evidence of conducting an on-site visit by the LD. The findings include: 1. It was the practice of the laboratory to perform high complexity testing. The laboratory director must be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. 2. On May 28th, 2025, at approximately 12:00 pm, the TS and LD confirmed that the laboratory did not maintain any evidence of performing on-site visits by the LD for 2 of 2 years. 3. The laboratory's testing declaration form, signed by the laboratory director on May 15, 2025, stated that the laboratory performed approximately 1,246,362 tests annually.