

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0871568	(X3) Date Survey Completed 03/05/2025
Name of Provider or Supplier Genentox Laboratories, Llc	Street Address, City, State 2001 E First St, Ste 109, Santa Ana, 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 the review of the American Proficiency Institute (API) proficiency testing (PT), and the College of American Pathologists (CAP) PT testing records, six (6) randomly selected patient test records, and interviews with the testing personnel (TP); it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for LDH for the first event of 2024 and Creatinine (Urine) for the third event of 2024. The findings include: 1. Review of PT records for the first event of 2024 (Q1-2024), API reported an unsatisfactory score report as follows: LD/LDH PT Q1-2024 Overall score: 60% Specimen Reported Expected CH-01 105 69-104 * CH-02 639 423-635 * CH-03 482 324-487 CH-04 145 98-148 CH-05 850 568-854 * indicates unacceptable result 2. Review of CAP - PT records for Creatinine (Urine) Microgenetic DRI for the third event of 2024, for out of ten PT samples tested a score of 50% was obtained which is unacceptable. 3. TP confirmed by interview on March 5, 2025, at approximately 11:00 a.m. that the laboratory obtained the PT scores mentioned in statements #1 and #2 above. 4. According to the laboratory's testing declaration submitted on the day of the survey March 5, 2025, the laboratory performed approximately 18,000 Routine Chemistry tests, including LD/LDH and approximately 8,140 Urine Creatinine tests, during the time the laboratory received unsatisfactory proficiency testing results.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the validation/verification documentation and interview with the laboratory technical supervisor (TS) and testing personnel (TP); the laboratory failed to have validation/verification plans, documents, and new protocols approved, signed, and dated by the current laboratory director before use. The findings included: 1. On the day of the survey March 5, 2025, at approximately 1:00 p.m. the validation /verification records including new protocols in place for various new tests validated /verified (Abbot HIV, Hepatitis panel, AIC, TSH, Vit B12, etc.) in the laboratory had not been approved, signed, and dated by the laboratory director before placing them in use. 2. The TS and TP confirmed by interview on March 5, 2025, that the laboratory failed to have the laboratory director approve, sign, and dated validation/verification plan, records, and new protocols for testing performed in the laboratory with the effective date and the laboratory director's signature. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 77,698 patients' samples annually.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's quality control records, six (6) randomly chosen patient records, and interviews the technical supervisor (TS) and testing personnel (TP); the laboratory failed to perform control procedures using the number and frequency specified by the manufacturer to support control procedures for Microbiology Gastrointestinal (GI) panel. Findings included: 1. Review of a randomly chosen patients test results, for one (1) out of six (6), the laboratory failed to run Quality Controls on May 22, 2024. 2. The TP confirmed by interview unable to find QC results for GI panels tested on 5/22/2024. 3. Based on the laboratory testing declaration submitted at the time of the survey March 5, 2025, the laboratory reported approximately 22,634 Microbiology testing samples annually including GI panels.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the 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:
ased on surveyor's review of laboratory's proficiency testing records, validation /verification of new tests, six (6) randomly selected patients' test samples results, and interview with the laboratory's technical supervisor and testing personnel testing personnel on March 5, 2025; the laboratory director failed to provide effective analytical direction of the laboratory. See D2087, D 5407, and D5445.