

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0871568	(X3) Date Survey Completed 02/06/2024
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
D5467	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g)</p> <p>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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control material, calibrator, and interview with the laboratory technical supervisor on February 6, 2024, at 12:00 pm, the laboratory failed to use different lot's control material from the calibrator. The findings include: 1. The laboratory used an LC-MS/MS method to detect various drugs in the patient sample. It used a calibrator to calibrate the system by a standard curve and ran quality control each time of testing. However, it used the calibrator material from the same lot of quality control material. Therefore, the validity of the test method cannot be assured and might have had harmed patient. 2. The laboratory technical supervisor on February 6, 2024, at 12:00 pm, affirmed that the laboratory used the calibrator material from the same lot of quality control material. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/2/2024, stated that the laboratory performs approximately 201,872 LC-MS tests, annually.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory</p>

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 reapportions 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 Surveyor review of laboratory's policy & procedure, quality control and patient test records, and interview with the laboratory technical supervisor on February 6, 2024, at 12:00 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D5467, D6093 and D6107.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's quality control material, calibrator, and interview with the laboratory technical supervisor on February 6, 2024, at 12:00 pm, the laboratory director failed to ensure that the laboratory established and maintained the quality control programs to assess the quality of laboratory services provided. The findings include: See D5467.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's personnel records, and interview with the laboratory technical supervisor on February 6, 2024, at 11:50 am, the laboratory director failed to specify, in writing, the responsibilities and duties of each individual involved in the laboratory operation including consultants and supervisors. The findings include: The laboratory's personnel report form signed by the laboratory director on February 2, 2024, showed that it had 1 TS/GS and 3 TP. However, the laboratory did not have any record showing that the laboratory director have specified, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each

individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.