

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2172174	(X3) Date Survey Completed 08/11/2025
Name of Provider or Supplier Genco Labs, Llc	Street Address, City, State 7 Sycamore Way, Unit 9, Branford, CT	
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 record review and staff interview, the laboratory failed to follow their established policy to perform split sample Proficiency Testing (PT) twice yearly in the subspecialty of Toxicology. Findings include: 1. Record review on 08/11/2025 of the laboratory's established "Split Sample Proficiency Testing" policy revealed the following: a. "When commercial PT is not available for all testing done in the lab, split sample testing can be employed." b. "Five samples will be sent twice yearly." 2. Record review on 08/11/2025 of the laboratory's established "Quality Assurance Timetable" policy revealed "LCMS Split sample testing (Feb & Aug)". 3. Record review on 08/11/2025 of the PT records revealed lack of documentation for the split sample PT performance as follows: a. Two of Two (February and August) 2024. b. One of Two (February) 2025. 4. Staff interview on 08/11/2025 at 1:00 PM confirmed the findings in 3 above. 5. The laboratory performs 637,236 tests annually in the subspecialty of Toxicology.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on surveyor observation, record review and staff interview, the laboratory failed to follow their established general laboratory quality assessment policies and procedure to correct problems when expired quality control materials were used in the subspecialty of Toxicology. Findings include: 1. Surveyor observation on 08/11/2025 at 09:35 AM during the laboratory tour, revealed a refrigerator/freezer in use to store "LC/MS/MS New QC Stock Solutions". 2. Surveyor observation on 08/11/2025 at 09:36 AM of the freezer contents revealed the aliquot vials in use labelled, "Oral Fluid (OF)- SS0F03242025, Exp- 06/24/2025, Weekly - 50:450." 3. Record review on 08/11/2025 of the laboratory's 'Quality Control (QC) Monthly Review: Toxicology LCMS & UDS' logs for the month of June and July of 2025 revealed the General Supervisor (GS) and the Technical Supervisor (TS) verified the disposal of expired reagents, QCs, and calibrators. 4. Record review on 08/11/2025 of the laboratory's 'LCMS Monthly Maintenance Log' for June and July of 2025 revealed the 'Check expiration dates on STDs, QCs, mobile phases' step checked off as completed by the GS. 5. Staff interview on 08/11/2025 at 9:30 AM with the laboratory general supervisor and technical supervisor confirmed the above findings. 6. The laboratory performs 637,236 tests annually in the subspecialty of Toxicology.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on surveyor observation, record review and staff interview, the laboratory failed to ensure the Quality Control (QC) stock solution used for oral fluid testing did not exceed the expiration date when used for the Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) in the subspecialty of Toxicology. Findings include: 1. Surveyor observation on 08/11/2025 at 09:35 AM during the laboratory tour, revealed a refrigerator/freezer in use to store "LC/MS/MS New QC Stock Solutions". 2. Surveyor observation on 08/11/2025 at 09:36 AM of the freezer contents revealed the aliquot vials in use labeled, "Oral Fluid (OF)- SS0F03242025, Exp- 06/24/2025, Weekly - 50:450." 3. Record review on 08/11/2025 of the laboratory's "LC/MS/MS New QC Stock Solution Lot Record" log revealed 2 OF standard lot numbers (SLN) as follows: a. "SLN: OFSS03242025, Date/Time prepared: 03/24/2025, Expiration date: 06/24/2025, Verification Acceptable: YES." b. "SLN: OFSS07152025, Date /Time prepared: 07/15/2025, Expiration date: 10/30/2025, Verification Acceptable: NO." 4. Record review on 08/11/2025 of the "OF runs since 6/24/2025" report revealed the laboratory performed 181 OF toxicology confirmation tests using expired QC solution listed in 2(a) above in the subspecialty of toxicology. 5. Staff interview on 08/11/2025 at 09:40 AM with the General Supervisor (GS) confirmed the above findings. He/she further stated that the laboratory has been using the expired stock solutions due to the inability to obtain verification acceptability of the new lot (OFSS07152025) prior to use.