

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0655571	(X3) Date Survey Completed 04/30/2026
Name of Provider or Supplier Genova Diagnostics	Street Address, City, State 63 Zillicoa Street, Asheville, NC	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observation 4/29/26, review of the MICRO (AVL) 100.7 Media Quality Control policy, and interview with the microbiology TS (Technical Supervisor) on 4/30/26, the laboratory failed to discard expired media. Findings: 1. During a tour of the laboratory at approximately 3:00 p.m. on 4/29/26, the surveyor observed 2 open boxes of expired Corn Meal Agar in the microbiology walk-in refrigerator number D6547 available for use, including: a. 1 box labeled REF 5339 Lot 2510002M Expiration 4/3/26, marked opened for QC 1/27/26, containing 1 package with 5 plates. b. 1 box labeled REF 5339 Lot 2510002M Expiration 4/3/26, marked opened 2/4/26, containing 4 packages with 10 plates each. 2. Review of the MICRO (AVL) 100.7 Media Quality Control policy revealed the quality control process for Corn Meal Agar. Page 2 of the policy stated, "If the media performs as expected, record the lot number, date received, expiration date, on the QC ordered in Total QC." The policy also stated, "Records will be reviewed monthly." The policy did not include instructions for the disposal of expired supplies. 3. During an interview at approximately 9:30 a.m. on 4/30/26, the TS stated expired supplies should be discarded and the supervisor should be notified if stock is low. The TS stated that expirations are checked during monthly inventory counts at the end of the month and the short dates are mentioned during huddles. At approximately 10:20 a.m., the TS confirmed there was no policy that specifically addressed discarding expired supplies.</p>