

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0655571	(X3) Date Survey Completed 05/16/2024
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based upon review of the iCAP Q ICP-MS Operating Manual, review of 2023 and 2024 maintenance logs and interview with TS (technical supervisor) #5 on 5/15/24, the laboratory failed to perform and document maintenance tasks required by the manufacturer of the ICP-MS instrument. Findings: Review of the iCAP Q ICP-MS Operating Manual revealed the following in Chapter 8: Maintenance: Table 8.1: 1. Item: Mass Analyzer Air Filter, Procedure: Check fan, Frequency: Monthly 2. Item: Sogevac Fore Vacuum Pump, Procedure: Check oil, Frequency: Daily 3. Item: Sogevac Fore Vacuum Pump, Procedure: Check gas ballast valve, Frequency: Monthly Review of 2023 and 2024 maintenance logs for the ICP-MS instrument did not reveal documentation of the performance of the following maintenance tasks: 1. Monthly fan check of mass analyzer air filter 2. Daily oil check of Sogevac Fore vacuum pump 3. Monthly gas ballast valve check of Sogevac Fore vacuum pump During interview at approximately 11:20 a.m. on 5/15/24, TS #5 stated in a Teams chat that the aforementioned maintenance tasks are performed; however, they are not documented.</p>