

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0255349	(X3) Date Survey Completed 10/14/2020
Name of Provider or Supplier Genova Diagnostics Inc	Street Address, City, State 3425 Corporate Way, Duluth, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 14, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure protection from physical, chemical, and biochemical hazards as required. Findings include: 1. Observation of the safety shower logsheets in the Molecular Chemistry hallway during the laboratory tour on 10/14/2020 at approximately 12:45 p.m. revealed required weekly function checks were not documented for the following time periods: 2018 (July -- 2 out of 5 weeks; September and November -- 3 out of 4 weeks); 2019 (April -- 3 out of 4 weeks; May and October -- 4 out of 5 weeks); 2020 (January and February -- 3 out of 4 weeks). 2. An interview with the Senior Quality Assurance Manager in the Molecular Chemistry hallway on 10/14/2020 at approximately 1:00 p. m. confirmed the lack of safety shower function check documentation for the aforementioned dates.</p>