Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0255349	03/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Genova Diagnostics Inc	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 March 6, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to test the PT samples with the laboratory's regular patient workload by testing personnel (TP) who routinely perform the laboratory tests. Findings include: 1. College of American Pathologists (CAP) PT document review revealed Staff #10 (CMS 209) tested the PT samples for all 3 Chemistry (Ferritin) PT events in 2017. 2. An interview with the quality systems manager on 3/6/18 in a conference room at approximately 3 p.m. confirmed Staff #10 (CMS 209) performed all 3 Chemistry (Ferritin) PT events in 2017.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and maintenance logs and staff interview, the laboratory failed to follow the written procedures for all tests, assays, and examinations as required. Findings include: 1. SOP review and high performance liquid chromatography-mass spectrometry (HP /LCMS) 2017 and 2018 guanosine maintenance logs revealed the analytical column was not changed monthly as required in the SOP. 2. An interview with the quality systems manager on 3/6/18 in a conference room at approximately 3 p.m. confirmed the HP/LCMS analytical column was not changed monthly for 2017 and 2018 as required in the laboratory SOP.