Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2151111	**(X3) Date Survey Completed** 01/18/2023
Name of Provider or Supplier Neogenomics Laboratories Inc	**Street Address, City, State** 900 Ocean Dr Apt 504, Juno Beach, FL	
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	An announced CLIA recertification survey was conducted at NeoGenomics Laboratories Inc on 01/18/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Laboratory Director and the Site Quality Manager, the laboratory failed to document the evaluation of Flow cytometry quality controls and the evaluation of fluorescence in situ hybridization (FISH) testing quality controls for two out of two years (2020 - 2022). The findings included: Review of the CMS 116 Application for Certification, signed and dated (01/16/2023) by the Laboratory Director revealed the laboratory was a "Analysis only" laboratory. The patient's specimens were tested at the main laboratory. Record review of quality control records for Flow cytometry testing and FISH testing revealed the laboratory had not documented the evaluation of quality controls. On 01/18/2023 at 12:30 p.m., during an interview the Laboratory Director stated she had never had to document quality control for Flow cytometry or FISH testing. On 01/18/2023 at 12:45 p.m., during an interview the Site Quality Manager stated he did not know that the Laboratory Director should be reviewing and documenting the quality controls for Flow cytometry and FISH testing.