

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 99D2023356	(X3) Date Survey Completed 02/29/2024
Name of Provider or Supplier Genetype Inc	Street Address, City, State 60-66 Hanover Street, Not Available, FN	
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
D5791	<p>Based on quality assessment policies and procedures record review and interview with laboratory personnel on February 28, 2024 at 1:00 pm, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings included: a. According to the laboratory's written protocol titled "Generation of Patient Reports in DNAnexus (TSM-STP-7, ver #3)," section 8, Acceptance Criteria, described the laboratory's criteria for acceptability of various quality control parameters. These quality control parameters included acceptance criteria for the positive quality control results and array call rates, and review of concordance results, GSA controls analysis charts, and potential report generation errors. b. On February 28, 2024 at 1:15 pm, laboratory personnel confirmed that the laboratory maintained no written quality assessment policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified for the quality control activities described in the laboratory's written protocol titled "Generation of Patient Reports in DNAnexus (TSM-STP-7, ver #3)." c. According to laboratory records, the laboratory performed and reported approximately 247 patient tests annually involving the use of this written protocol.</p>