

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2290518	(X3) Date Survey Completed 11/20/2025
Name of Provider or Supplier Genomics Inc	Street Address, City, State 175 Crossing Blvd, Framingham, MA	
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 CLIA recertification survey was conducted for the Genomics, Inc laboratory on 11/24/2025 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D6005	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p> <p>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory records and interview with the Director of Quality Management the Laboratory Director (LD) failed to visit the laboratory at least once every six months in 2025. Findings include: 1. The surveyor reviewed the laboratory's 2024 and 2025 quality management records. The review revealed documentation of a LD visit on 11/11/2025. There were no other documented visits by the LD in 2025. 2. Interview with the Director of Quality Management on 11/20/2025 at 10:45am confirmed that the LD had not visited the laboratory at least once every 6 months in 2025. 3. The laboratory performs 29,918 routine chemistry tests annually.</p>