

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1053083	(X3) Date Survey Completed 06/09/2026
Name of Provider or Supplier Quanterix Corporation	Street Address, City, State 900 Middlesex Turnpike, Building 1, Billerica, 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 Quanterix Corporation laboratory on 06/09/2026 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS), the laboratory did not assess the General Supervisor (GS) in accordance with their CLIA responsibilities. Findings Include: 1. Record review on 6/9/2026 of the laboratory CMS 209 form revealed the laboratory had three general supervisors. 2. Record review on 6/9/2026 of the laboratory's 2024, 2025, and 2026 to date personnel records revealed 1 of 3 GS did not have documented competency evaluation based on their CLIA responsibilities. 3. During an interview with the TS on 6/9/2026 at 9:51 AM, the TS confirmed that the competency of 1 of the 3 GS was not documented. 4. The laboratory performs 9,018 tests annually.</p>