

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0967945	(X3) Date Survey Completed 07/16/2026
Name of Provider or Supplier Ou Health Genetics Laboratory	Street Address, City, State 1122 Ne 13th St, Suite 1400, Oklahoma City, OK	
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	The validation survey was performed on 07/16/2026. A standard-level deficiency was cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interviews with the Operations Manager, Patient Safety/Regulatory Manager, and Laboratory Quality and Safety Manager, the laboratory failed to follow their written policy to assess the competency of the Clinical Consultant and Technical Supervisors, based on the position responsibilities as listed in Subpart M, for one of one person serving as a Clinical Consultant, and for three of three persons serving as Technical Supervisors during the review period of July 2024 through the current date. Findings include: I. CLINICAL CONSULTANT (1) A review of the laboratory policy titled, "Competency Program" under the section "Policy" stated "Document the performance of individuals with responsibilities in the role of Technical supervisor, Clinical Consultant, and/or General Supervisor who are not listed as the CLIA laboratory director. The CLIA lab director assesses the competency, annually."; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of July 2024 through the current date identified competencies, based on the position responsibilities, had not been documented as performed prior to 07/15/2026 for one of one individual serving as the Clinical Consultant; (3) The findings were reviewed with the Operations Manager who stated on 07/16/2026 01:50 pm, the policy had not been followed. II. TECHNICAL SUPERVISOR (1) A review of the laboratory policy titled, "Competency Program"

under the section "Policy" stated "Document the performance of individuals with responsibilities in the role of Technical supervisor, Clinical Consultant, and/or General Supervisor who are not listed as the CLIA laboratory director. The CLIA lab director assesses the competency, annually."; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of July 2024 through the current date identified competencies, based on the position responsibilities, had not been documented as performed for the assessment period of 2024 for three of three individuals listed as the technical supervisors; (3) The findings were reviewed with the Patient Safety /Regulatory Manager, and Laboratory Quality and Safety Manager who stated on 07 /16/2026 01:48 pm, the policy had not been followed.