

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0143149	(X3) Date Survey Completed 06/14/2023
Name of Provider or Supplier Men's Fertility Laboratory	Street Address, City, State 900 Northern Blvd Suite 230, Great Neck, NY	
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 exempt-state validation survey was conducted at the Men's Fertility Laboratory on June 14, 2023, by a CMS New York CLIA Branch Location federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiency was found during CLIA exempt-state validation survey performed on June 14, 2023.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory standard operating procedure manual (SOPM) and interview with the laboratory director (LD), the laboratory failed to establish a complete competency assessment procedure to include the the assessment of new testing personnel at least semiannually during the first year the individual tests patient specimens and establish a procedure to perform competency assessment for supervisory personnel for their roles in the laboratory from June 2021 to June 2023. Findings Include: 1. On the day of survey, June 14, 2023, the laboratory could not provide semi annual competency assessments performed on testing personnel (TP) #2 during their first year of employment. 2. The laboratory could not provide supervisory competency performed for TP #1. 3. Review of the laboratory SOPM revealed, the laboratory didn't not establish a procedure to perform and document competency for testing personnel semi annually during the first year of employment and to perform a competency of TP performing supervisory roles in the laboratory. 4. The LD confirmed the findings above on June 16, 2023 around 12:50 PM.</p>