

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2081782	(X3) Date Survey Completed 06/04/2024
Name of Provider or Supplier Gago Center For Fertility (Lansing)	Street Address, City, State 1515 Lake Lansing Road Suite F, Lansing, MI	
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
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:</p> <ul style="list-style-type: none"> . Based on review of laboratory procedure manual, review of competency records for testing personnel and interview with the General Supervisor, the laboratory failed to ensure written competency assessment policies were followed for testing performed in 2022 and 2023. Findings include: 1. Review of laboratory competency assessments revealed that no documentation of competency assessments were found in 2023 for Testing Personnel #1 and Testing Personnel #2 and in 2022 for Testing Personnel #3. 2. An interview with General Supervisor on 06/04/2024 at 10:17 am, revealed that supporting documentation provided for Testing Personnel #1 for 2023, Testing Personnel #2 and Testing Personnel #3 from an affiliate location, not the laboratory. 3. A review of the laboratory's "Laboratory Personnel Training/Competence Checklist" policy revealed a section stating, "In order to establish and maintain accurate test performance in the Laboratory associated with Gago Center for Fertility all employees that perform laboratory functions are required to prove competency." 4. An interview with General Supervisor on 06/04/2024 at 10:23 am confirmed the competency assessments were not performed.