

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2097127	<b>(X3) Date Survey Completed</b>  10/27/2023
<b>Name of Provider or Supplier</b>  Molecular Characterization Laboratory	<b>Street Address, City, State</b>  459 Miller Dr, Frederick, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<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 a review of laboratory personnel competency assessment records and an interview with the Quality Assurance Manager, the laboratory failed to establish written policies and procedures to assess Technical Supervisors (TS) and General Supervisors (GS) for competency in 2021 and 2022. Findings Included: 1. The personnel form CMS-209 filled out by the laboratory at the time of the survey listed 3 TS technical supervisors and 2 GS General Supervisors for the laboratory. 2. Review of the competency assessment records, revealed, that the laboratory did not establish a TS and GS competency assessment policy. 2. Interviews with the Quality Assurance Manager on 10/27/2023 at 11:45 am confirmed they did not establish a written policy to assess TS and GS for competency.</p>