

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2277972	(X3) Date Survey Completed 12/05/2023
Name of Provider or Supplier Mclaren Macomb	Street Address, City, State 21510 Harrington, Clinton Township, 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: . Based on record review and interview with the Technical Consultant, the laboratory failed to establish competency assessment policies to assess the competency of its staff serving as clinical and technical consultants for 1 (November 2023 to December 2023) of 1 month since the laboratory began testing. Findings include: 1. A review of the laboratory's personnel competency assessments revealed a lack of assessments for the Clinical Consultant and the Technical Consultant. 2. An interview on 12/5/23 at 10:50 am with the Technical Consultant confirmed the laboratory had not established a competency assessment procedure to include assessing clinical and technical consultants.</p>