

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0914071	<b>(X3) Date Survey Completed</b>  04/14/2025
<b>Name of Provider or Supplier</b>  Karmanos Cancer Institute - Lapeer	<b>Street Address, City, State</b>  1295 Barry Drive Suite B, Lapeer, MI	
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><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 Manager of Clinic Operations, the laboratory failed to establish and follow written competency assessment policies for 2 of 2 Technical Consultants (TC1, TC2) as listed on the CMS-209 per CLIA regulation 493.1235. Findings include: 1. A review of the laboratory personnel documentation revealed a lack of competency assessments for the following: a. No competency assessments were conducted for TC1 for the years 2023, 2024 and 2025. b. No competency assessments were conducted for TC2 since promotion into new role in April 2024. c. The surveyor requested the missing documentation listed above at 10:30 am from TC2 and was unable to provide documents. 2. A review of the laboratory's personnel competency policies revealed the policy did not include assessments for Technical Consultants. 3. An interview with the Manager of Clinic Operations on 04/14/2025 at 10:45 am confirmed the lack of documentation listed above; and stated that the laboratory TC (Technical Consultant) competency assessments are conducted every 2 years; however it is not indicated in the laboratory policy.</p>