

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2103868	<b>(X3) Date Survey Completed</b>  07/01/2025
<b>Name of Provider or Supplier</b>  Apex Dermatology And Skin Surgery Center	<b>Street Address, City, State</b>  6820 Ridge Road, Suite 201, Parma, OH	
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 an interview with the Mohs Histotechnician (MH), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Clinical Consultant (CC), Technical Supervisor (TS) and General Supervisor (GS) based on the responsibilities of each position for the high complexity Mohs tissue biopsy testing procedures performed in the subspecialty of Histopathology. This deficient practice had the potential to affect 375 out of 375 patient Mohs tissue biopsy testing procedures performed between 10/08/2024 through 07/01/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 06/13/2025 and provided on the date of the inspection, revealed two out of two qualified and listed individuals; one as the Laboratory Director and sole CC and the second as the sole TS, GS and Testing Personnel (TP) to perform high complexity Mohs tissue biopsy testing procedures. 2. Review of the laboratory's "Mohs Surgeon/Technician COMPETENCY" policy and procedure, approved via signature and date by the Laboratory Director on 05/23/2025 and provided on the date of the inspection did not find any instructions to conduct CC, TS and GS competency assessments based on the CLIA responsibilities of the positions. 3. Review of the laboratory's competency assessment documentation for the sole TS, GS and TP found assessments conducted by the Laboratory Director on 05/30/2024 and 06/12/2025 including the six required components for TP as well as the competency assessment based on the CC responsibilities. 4. The Inspector requested the laboratory's competency assessment policy and procedure based on the responsibilities of the CC, TS and GS and the sole</p>

TS and GS's 2024 and 2025 competency assessment documentation from the MH. The MH confirmed the laboratory did not establish a policy and procedure to assess the CC, TS and GS based on the responsibilities of each position and did not conduct these competency assessments on the sole TS and GS in 2024 and 2025. The MH was unable to provide the requested documentation on the date of the inspection. The interview occurred on 07/01/2025 at 10:17 AM.