

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1040200	<b>(X3) Date Survey Completed</b>  03/04/2025
<b>Name of Provider or Supplier</b>  Pinnacle Dermatology	<b>Street Address, City, State</b>  104 N Haven Rd Ste 7, Elmhurst, IL	
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>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to perform bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for two of four events reviewed in 2023 and 2024. Findings include: 1. Review of laboratory policies and procedures revealed the document titled, "Quality Assurance", which stated, under "Mohs Micrographic Surgery", "Slides will be pulled bi-annually at random from each year in which Mohs surgery is performed. A doctor besides the one who performed the surgery will read the slides to ensure that both agree on the diagnosis and that the case is clear." 2. Review of laboratory records revealed that two of four bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) events reviewed for 2023 and 2024 were not reviewed by a secondary Mohs surgeon (MS). Year: MS #: Reviewing MS #: 1st half 2023 1 2 2nd half 2023 1 2 1st half 2024 1 No documentation 2nd half 2024 1 No documentation 3. Interview with the laboratory representative on 03/04/2025, at 12:23 pm, confirmed the laboratory failed to perform bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for two of four events reviewed in 2023 and 2024.</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify</p>

failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory director failed to ensure that the quality assessment program was maintained to assure the laboratory performed bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for two of four events reviewed in 2023 and 2024. See D5217.