

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0955875	<b>(X3) Date Survey Completed</b>  07/08/2025
<b>Name of Provider or Supplier</b>  Pinnacle Dermatology Grand Blanc	<b>Street Address, City, State</b>  8245 N Holly Road, Suite 101, Grand Blanc, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 record review and interview with the Mohs Tech (MT), the laboratory failed to verify the accuracy of its testing at least twice annually for two (July 2024 to December 2024, January 2025 to June 2025) of four periods reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of twice annual verification of accuracy for microscopic histopathology testing had not been performed for two periods: a. July 2024 - December 2024 b. January 2025 - June 2025 2. An interview on 7/7/25 at 2:00 pm with the MT confirmed the laboratory had not performed verification of accuracy testing for 1 year.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with Mohs Tech (MT), the laboratory failed to ensure reagents were not used beyond the expiration date for 1 of 1 bottle of reagent (Vintage Bluing). Findings include: 1. During a tour of the laboratory on 07/07/2025</p>

at 1:30 pm, the surveyor observed 1 bottle of Vintage Bluing reagent with an expiration date of 04/30/2025. 2. An interview conducted on 07/07/2025 at 3:45 p.m., the MT confirmed expired reagent was available for use.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

(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 failures in quality as they occur;

This STANDARD is not met as evidenced by:  
Based on record review and interview with Mohs Tech (MT), the laboratory failed to follow established quality assessment policies and procedures for six (2nd quarter 2024, 3rd quarter 2024, 4th quarter 2024) of eight quarters reviewed. Findings include: 1. A record review of the laboratory's quality assessment documentation revealed a lack of quality assessments documentation for four quarters in 2024 and two quarters in 2025 2. A review of the laboratory's "Policy on Quality Assurance - Quarterly Checklist" states in section titled "QUALITY ASSURANCE PLAN," first sentence, "Quarterly, the technician will select on Mohs surgical case for a process quality assurance check...", "...the approved quality assurance checklist will be filled out for this case.... These forms will be kept.... for two years." 3. An interview conducted on 07/07/2025 at 2:00 pm with the MT confirmed that the laboratory quality assessment checklists were not present.