

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2090351	(X3) Date Survey Completed 07/08/2025
Name of Provider or Supplier Pinnacle Dermatology Villa Linde	Street Address, City, State 2256 W Hill Road, Flint, 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
D5417	<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 dates for 5 of 8 bottles of reagents. Findings include: 1. During a tour of the laboratory on 07/07/2025 at 9:30 am, the surveyor observed expired reagents: a. 1 bottle of Blue Tissue Marking Dye with an expiration date of 7/31/2023. b. 2 bottles of 10% Formalin Fixative with an expiration date of 09/6/2020. c. 1 bottle of Eosin Working Solution with an expiration date of 03/06/2020. d. 1 bottle of 1% Acid Alcohol with an expiration date of 02/28 /2025. 2. An interview conducted on 07/07/2025 at 11:45 a.m., the MT confirmed expired reagents were available for use.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Mohs Tech (MT), the laboratory failed to follow established general laboratory systems quality assessment policies and procedures for 3 (March - June 2024, July - September 2024. October - December</p>

2024) of 8 quarters reviewed. Findings include: 1. A record review of the laboratory's quality assessment documentation revealed quality assessments documentation was not present for 3 quarters in 2024 (2nd quarter, 3rd quarter, 4th quarter). 2. A review of the laboratory "Policy on Quality Assurance - Quarterly Checklist" revealed 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 11: 13 am with the MT confirmed that records were not present.