

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2129169	(X3) Date Survey Completed 05/22/2025
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 1703 Calumet Avenue, Valparaiso, IN	
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
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 interviews, the laboratory failed to monitor and maintain the quality assessment program quarterly as required by policy from March 2021 to the date of the survey. Findings included: 1. Review of "Quarterly Quality Assurance Checklist", signed by the Laboratory Director (SP-02) indicated the last quality assurance review was completed on 3-19-2021. 2. In an interview on 5-22-2025 at 1:45 pm, SP-01 (Testing personnel) confirmed the date of the last quality assurance checklist was completed on 3-19-2021 and no quality assurance meeting(s) had been conducted since 3-19-2021. 3. "Policy on Quality Assurance -Quarterly Checklist", reviewed by the laboratory director (SP-02) on 9-2024, read, "this policy is designed to monitor and evaluate the ongoing and overall quality of the total testing process" by selecting one surgical Mohs micrographic surgery (Mohs) case quarterly for a quality assurance check. 4. The following patients (PT) had Mohs performed without a quarterly quality assessment check. Patient (PT) Date PT #1 3/22/24 PT#2 4/19/24 PT#3 5/24/24 PT#4 6/21/24 PT#5 7/19/24 PT#6 8/23/24 PT#7 9/20/24 PT#8 11/17/23 6. Annual test volume for histopathology is 200.</p>