

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0955875	(X3) Date Survey Completed 10/03/2022
Name of Provider or Supplier Pinnacle Dermatology Grand Blanc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Mohs Supervisor, the laboratory failed to perform and document microscope maintenance annually as specified in the laboratory's policy for 11 (November 2021 to October 2022) of 11 months since microscope maintenance was due to be performed. Findings include: 1. The surveyor observed the microscope in the mohs laboratory on 10/3/22 at 1:33 pm. The microscope had a sticker noting the service date was 11/30/20 and the next service was due 11/21. 2. A review of the laboratory's "Policy on Quality Assurance and Procedure- Mohs Surgery" revealed a section stating, "Microscope, cleaning of ocular eye pieces and stage. Preventative maintenance annually." 3. An interview with the Mohs Supervisor on 10/3/22 at 1:56 pm confirmed the laboratory had not performed and documented annual preventative maintenance for the microscope according to its policy.</p>