

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0223251	(X3) Date Survey Completed 06/06/2024
Name of Provider or Supplier Robert N Deangelis Md Ltd	Street Address, City, State 8346 Traford Lane Suite 101, Springfield, VA	
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
D0000	An announced CLIA recertification survey was conducted at Robert N. DeAngelis MD LTD on June 6, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
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 a tour, review of laboratory policies and procedures, lack of documentation, and interview, the laboratory failed to follow their established policy of service /maintenance for one (1) of 1 microscope utilized for reading dermatopathology slides from September 2022 until the date of the survey on June 6, 2024. The findings include: 1. During a tour with the laboratory director (LD) at 9:30 AM, the surveyor noted a Ernst Leitz (Serial #020441.012) microscope in use for the reading of dermatopathology slides. 2. A review of the laboratory records revealed a lack of documentation of microscope service for the Leitz microscope from September 2022 until the date of the survey on June 6, 2024. 3. Review of the laboratory procedure manual revealed a policy, "Equipment Quality Control-Microscope", with the statement, "1. Microscope stage and ocular eye pieces are to be cleaned prn but less than or equal to 1 year." and a handwritten note with the statement, "Microscopes will be kept free of oil and dust with official lens wipe and thorough cleaned periodically</p>

by Alpha & Omega Instrument Services." The surveyor requested to see documentation of the microscope maintenance from September 2022 until the date of the survey. No documentation was provided. 4. In an interview with the LD on June 6, 2024 at 9:30 AM the LD stated, "I did not schedule the maintenance for 2022 or 2023. When I tried to schedule the maintenance for this year, the number for Alpha & Omega was no longer in service. I have a telephone number for another company that I will contact for service."