

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2014610	(X3) Date Survey Completed 03/07/2023
Name of Provider or Supplier Derm One, Pllc	Street Address, City, State 180 B East Main Street, Radford, 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 the Derm One, PLLC (Radford) on 03/07/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5217	<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:</p> <p>A. Based on the review of policy and procedures (P&P), peer review records, lack of documentation and interview, the laboratory failed to follow the established P&P for proficiency testing (PT) peer reviews conducted semi-annually in the calendar year 2022. Findings include: 1. Review of the P&P revealed the policy "Proficiency Testing Mohs Micrographic Surgery Skin Specimens" that stated, "Semi-annually, the tech or risk manager will send pathology, the original slides, the surgical case number, and send it for a microscopic examination by a board-certified dermatopathologist." 2. Review of available PT peer review records for the calendar years 2021 and 2022 revealed lack of documentation of the PT peer review performed semi-annually for the calendar year 2022: 07/01/21, 10/21/21 and 06/09/22. No other documentation was available for review upon request. 3. In an interview with testing personnel (TP) A on 03/07/23 at approximately 09:30 AM, they stated, "We were bought out by a new company in Florida in 8/2020. The company instructed us to send all peer reviews to them. We have had difficulty receiving results." 4. An exit interview with TP A on 03/07/23 at approximately 10:45 AM confirmed the findings. B. Based on the review of policy and procedures (P&P), peer review records, lack of documentation and interview, the proficiency testing (PT) peer review reports failed to include date of review by reference pathologist, diagnosis of specimen by reference</p>

pathologist, and name and address of both referring and reference laboratory for six of six reports reviewed at the date of survey on 03/07/23. Findings include: 1. Review of the P&P revealed the policy "Proficiency Testing Mohs Micrographic Surgery Skin Specimens" that stated, "Semi-annually, the tech or risk manager will send pathology, the original slides, the surgical case number, and send it for a microscopic examination by a board-certified dermatopathologist. No differential diagnosis will be offered with the specimen." 2. In an interview with testing personnel (TP) A on 03/07/23 at approximately 09:30 AM, they stated, "We were bought out by a new company in Florida in 8/2020. The company instructed us to send all peer reviews to them. We have had difficulty receiving results." 3. Review of six PT peer review records revealed lack of documentation of date of review by reference pathologist, diagnosis of specimen by reference pathologist, and name and address of both referring and reference laboratory for six of the six following reports: 21M-26259, 21M-26946, and 21M-27145; 22M-27315, 22M28055, and 22M-27626. 4. An exit interview with TP A on 03/07/23 at approximately 10:45 AM confirmed the findings.