

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2148650	(X3) Date Survey Completed 06/15/2022
Name of Provider or Supplier District Dermatology	Street Address, City, State 6711 Whittier Avenue, Suite 101, Mclean, 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 District Dermatology on June 15, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited 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: Based on a review of procedures, proficiency testing logs, and an interview, the laboratory failed to perform Mohs Micrographic skin specimen testing accuracy checks by peer review every six (6) months per their policy during calendar years 2020 and 2021 . Findings include: 1. Review of the laboratory's procedure manual revealed a policy for proficiency testing of Mohs micrographic surgery skin specimens ("Quality Control" page 4). The written policy stated "Every six months the director will randomly select a minimum of three cases that have been processed by the laboratory and forward those to a third party laboratory for compliance diagnosis. This will validate the original diagnosis and comply with CLIA for proficiency standard". 2. Review of the laboratory's proficiency documentation for calendar year 2020 up to the date of survey on 6/15/22 revealed the following documentation for Mohs micrographic split sample testing sent out for peer review on April 11, 2022: six cases from 2020 (accession numbers: 0020-003, 0020-0014, 0020-039, 0020-044, 0020-049, 0020-068); six cases from 2021 (accession numbers: 0021-012, 0021-039, 0021-080, 0021-132, 0021-166, 0021-228). The inspector requested to review peer review that was performed in 2020 and 2021. No documentation was available for review. The inspector inquired as to the reason the cases were not pulled every six months in 2020 and 2021 as outlined in the quality control policy. The</p>

histotech stated on 6/15/22 at approximately 2:30 PM, "In April, we went back and pulled cases for each year and sent them out for peer review. The cases were not pulled every six months in 2020 or 2021." 3. An exit interview with the histotech on 6/15/22 at approximately 4:00 PM confirmed the above findings.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on a tour, review of procedures, maintenance logs, lack of documentation, and interview, the laboratory failed to followed their established annual maintenance protocol for the microscope utilized in Mohs histopathology patient testing for two (2) of 2 years reviewed (2020 and 2021). Findings include: 1. During a facility tour at approximately 1:00 PM, the inspector noted an Olympus Model BX43F Serial #7C49531 microscope in the histopathology MOHS specimen processing area. 2. Review of the procedure manual revealed a policy ("Laboratory Microscope Maintenance Policy") that outlined: "The microscope will be inspected and serviced on at least a yearly basis by an independent microscope maintenance company or more often if needed due to performance issues." 3. A review of the laboratory's equipment maintenance logs (timeframe: 2020 to date of inspection on 6/15/22) revealed 1 record of annual maintenance completed by Alpha Omega Service, INC on 4/1/22. The inspector requested to review maintenance records for calendar year 2020 and 2021. No documentation was available. 4. An exit interview with the histotech at approximately 3:30 PM confirmed the above findings.