

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1085002	(X3) Date Survey Completed 03/03/2023
Name of Provider or Supplier Mid-Atlantic Skin Surgery Institute	Street Address, City, State 173 St Patricks Drive Suite 201, Waldorf, MD	
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
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 procedure manual and quality assurance (QA) review and interview with the histotechnician, the laboratory did not ensure that proficiency testing (PT) was performed at least twice annually. Findings: 1. The procedure, "Proficiency Testing" states, "Annually, the tech or Risk Manager will send the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatopathologist." The procedure, "Quality Assurance Program" states, "Proficiency testing is required for this service provided by our physician. It is suggested to submit 2 cases every 6 months to an outside pathologist. The Pathology report is attached to and retained as a method for proficiency testing." 2. The form used for recording PT documents the "Date of Surgery," the "Date Sent," and the date that the "outside pathologist" reviewed the slides. 3. A review of PT records from 2021 through 2023 showed that two cases were sent out for PT on 01/29/2021. 4. Two cases were documented as being sent out for PT on 12/30/2021 and two cases were documented as being sent out for PT on 12/05/2022, however all four of these cases were reviewed by the "outside pathologist" on 01/24/2023. There was no documentation that a second set of cases was sent out for PT in 2022. 5. During an interview on 03/03/2023 at 11:40 AM, the histotechnician stated that all four cases were probably sent together on 12/05/2022 and confirmed that the laboratory did not ensure that PT was performed at least twice annually.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interview with the histotechnician, the laboratory failed to ensure that tissue marking dyes used during Mohs surgery to mark patient tissue samples were not used after they exceeded their expiration dates. Findings: 1. During a tour of the laboratory at 10:15 AM, it was observed that 3 of 7 of the in-use "Avantik Tissue Marking Dyes" were expired. "Violet," lot # 107323 expired 09/30/2022; "Orange," lot # 112727 expired 12/31/2022; and "Black," lot # 101208 expired 06/30/2022. 2. During an interview on 03/03/2023 at 10:15 AM, the histotechnician confirmed that the tissue marking dyes were expired and stated that they would order new ones.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on procedure manual and record review and interview with the histotechnician, the laboratory did not document performance of routine preventive maintenance checks on the cryostat used for processing tissue samples for Mohs surgery. Findings: 1. The procedure, "Quality Control Policies and Documentation" states, "Air filter is cleaned as part of the maintenance every 6 months" and "Preventive maintenance and grounding checks are done 6 months." 2. A review of the "Cryostat Maintenance Checklist" from the most recent preventative maintenance (PM) performed on 11/08/2022 showed that cleaning the air filter and performing "grounding checks" was not included in the PM. 3. During an interview at 11:55 AM on the day of the survey the histotechnician stated that the laboratory staff did not perform the PM on the cryostat and confirmed that preventative maintenance was not documented.