

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2267009	(X3) Date Survey Completed 06/01/2023
Name of Provider or Supplier Mid Atlantic Skin Surgery Institute	Street Address, City, State 22738 Maple Rd #214, Lexington Park, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the standard operating procedure manual (SOPM) and interview with the histology technician (HT), the laboratory's SOPM failed to indicate that the proficiency testing (PT) specimens were evaluated twice annually and did not include instructions for transporting PT slides and MOHS (treatment of skin cancer) maps to the participating board certified dermatopathologists for evaluation. Findings: 1. The SOPM requires the laboratory to submit MOHS surgery slides to a participating board certified dermatopathologists for PT evaluation annually. According to the HT the slides are sent for evaluation in December and June of each year. 2. The SOPM</p>

requires the laboratory to submit MOHS surgery slides to a participating board certified dermatopathologists for evaluation annually, not in December and June of each year. 3. The HT stated that twice a year they randomly select a MOHS surgery slide and map to be sent to a participating board certified dermatopathologists for split sample PT review. 4. Review of the SOPM showed that there were no written instructions for the documentation of the removal of the slide, labeling, packaging, transportation and ensuring that the slide was received back into the laboratory for storage in a timely manner. 5. During the survey on 06/01/2023 at 11:15 AM, the HT confirmed that the SOPM did not contain all the required written instructions for sending PT specimens twice a year to a participating board certified dermatopathologists for PT review. II. Based on review of the SOPM and interview with the HT, the laboratory's SOPM failed to accurately identify how specimens are received into the laboratory for staining. Findings: 1. The "Specimen Acceptance or Rejection" SOPM states: "When the specimen is received in the laboratory, it must be received accordingly: 1. It must be transported in a secondary container. 2. It must be labeled with the patient's name, date, specimen site, corresponding map with stage number." 2. According to the HT the specimen is received on a piece of gauze that is on a paper towel that is labeled with the patient's name, date, and specimen site. 3. During the survey on 06/01/2023 at 11:15 AM, the HT confirmed that the SOPM did not contain an accurate description of how specimens are received in the laboratory. map with stage number." 2. According to the HT the specimen is received on a piece of gauze that is on a paper towel that is labeled with the patient's name, date, and specimen site. 3. During the survey on 06/01/2023 at 11:15 AM, the HT confirmed that the SOPM did not contain an accurate description of how specimens are received in the laboratory.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the staining station in the histology laboratory and interview with the histology technician (HT), the laboratory failed to label the staining dishes with identity and concentration of the contents. Findings: 1. Observation of the staining system showed that the containers for the stains did not have labels identifying the contents. The HT confirmed that the containers were not labeled identifying the contents of each container. 2. During the survey on 06/01/2023 at 11:15 AM, the HT confirmed that the containers used for staining in the histology department did not have labels identifying the contents of each solution used in the staining process.