

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1085002	(X3) Date Survey Completed 09/05/2018
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation in the Histology laboratory and interview with the histotech, the laboratory did not have an eyewash in the Histology laboratory where staining and slide preparation is being performed. Findings: 1. The laboratory is required to implement safety policies and procedures to ensure safety in the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. 2. The area where laboratory was staining and preparing slides was toured during the survey. Observation of the staining area showed that there was no eyewash attached to the sink to aid in flushing out the eyes of the histotech if they were to have been splashed with any stains or chemicals. 3. During the survey on 09/05/2018 at 1:15 PM the histotech confirmed that the an eyewash station was not in the area where the staining and slide preparation is being performed.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by:</p>

A. Based on review of the quality assurance (QA) records and interview with the laboratory director, the laboratory director did not ensure that the information being documented on the "Monthly Quality Assurance Checklist" was a reflection of the activities performed in the laboratory. Findings: 1. The "Monthly Quality Assurance Checklist" requires the user to mark a Y for yes; N for no; and N/A for not applicable by each item on the checklist indicating that the status of the item. 2. Review of the "Monthly Quality Assurance Checklist" records for 2017 and 2018 showed that the answer to all the questions on the checklist were Yes (Y). 3. The section on the "Monthly Quality Assurance Checklist" labeled "Specimens were handled and collected according to protocol" was marked with a "Y". Review of the laboratory records showed that there were 6 reports during 2017 and 2018 showing that there were problems with protocol being followed but they were not identified on the checklist. 4. The section on the "Monthly Quality Assurance Checklist" labeled "All proficiency test results were evaluated" was marked with a Y. Review of the laboratory records showed that proficiency was only tested in August 2017 and July 2018. The checklist indicates that proficiency testing is reviewed every month of the year. 5. The section on the "Monthly Quality Assurance Checklist" labeled "All personnel who perform tests have documented training for these tests", "All personnel who perform tests have read the procedure manual for those tests" and "Personnel evaluations were performed as necessary" were all marked with Y. Evaluation records show that these tasks are performed annually and not each month. 6. The "Monthly Quality Assurance Checklist" includes "All quality control/ calibrators were performed and were within acceptable limits before test results were reported." The laboratory does not have an analyzer that needs to be calibrated. 7. During the survey on 09/05/18 at 1:15 PM the laboratory director and histotech confirmed that the information being documented on the "Monthly Quality Assurance Checklist" was a reflection of the activities performed in the laboratory. B. Based on review of the procedure manual and interview with the laboratory director and histotech, the laboratory director did not ensure that the preventative maintenance was being performed every six months per the instructions in the procedure manual. Findings: 1. According to the preventative maintenance section of the procedure manual the laboratory is required to perform and document preventative maintenance every six month on the cryostats, air filters, strainer, fume hood, microscope and all other equipment used in the histology laboratory. 2. The laboratory records show that preventative maintenance was being performed annually instead of every six month. 3. During the survey on 09/05/18 at 1:15 PM the laboratory director and histotech confirmed that the preventative maintenance was not being performed every six months as required by the procedure manual.