Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2142636	03/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Anne Arundel Dermatology Berlin	9948 Main Street, Berlin, 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	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation in the Histology laboratory and interview with the laboratory manager, 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. The eyewash equipment was in the box next to the sink. 3. During the survey on 03/10/2020 at 12:00 PM the laboratory manager confirmed that the eyewash equipment was not attached to the sink faucet in the area where the staining and slide preparation is being performed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the laboratory manager, the laboratory's standard operating procedure manual (SOPM) did not include instructions for transporting proficiency testing (PT) slides to the main office. Findings: 1. The SOPM requires the laboratory to submit MOHS surgery (treatment of skin cancer) slides to a reference laboratory for PT evaluation twice a year. 2. The laboratory manager stated that the histotechnologist is notified twice a year to randomly select a MOHS surgery slide to be sent to the main office for split sample PT review. 3. 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. 4. During the survey on 03/10/2020 at 12:00 PM the laboratory manager confirmed that the SOPM did not contain all the required written instructions for the laboratory staff.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the "Laboratory Personnel Report (CLIA)" form (CMS-209), review of policies and procedures and interview with the laboratory manager, the laboratory director did not ensure that the policies for monitoring the laboratory staff included the technical supervisor, general supervisor and testing person. Findings: 1. The laboratory's CMS-209 lists the technical supervisor (TS), general supervisor (GS), and testing person (TP) as the same person. 2. According to the policies and procedures the laboratory director performs an annual review of all the laboratory records and documents that the documentation is acceptable. 3. The review does not clearly indicate that an evaluation was performed on the TS, GS and TP and that they were performing their duties and responsibilities in an acceptable manner. 4. During

	the survey on 03/10/2020 at 12:00 PM the laboratory manager confirmed that the laboratory policy and procedure manual did not include evaluation of the TS, GS, and TP on an annual basis.