Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1105196	11/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Maryland	11701 Livingston Road Ste 302, Fort Washington, 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 surveyor observation and interview with the laboratory staff and the technical supervisor (TS), the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. During an interview at 10:35 AM on the day of the survey, laboratory staff stated that the eye wash station was down the hall in a patient room. 2. During an interview on 11/19/2021 at 1:00 PM, the TS confirmed that the eye wash station was not located in the room where laboratory testing is performed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on procedure manual and record review and interview with the technical supervisor (TS), the laboratory failed to establish and follow written policies and

	procedures to assess employee and, if applicable, consultant competency. Findings: 1. The laboratory director delegated the responsibilities for the positions of clinical consultant (CC), general supervisor (GS), and TS to the testing person (TP) who performs histopathology testing in the laboratory. 2. During an interview on 11/19 /2021 at 1:00 PM the TP stated that they began work at the laboratory in November, 2020. 3. Procedure manual review showed that the laboratory did not have a written procedure for how to assess the competency of the TP in their role as the TP or in their duties as CC, GS, and TS. 4. Record review showed that there was no documentation that the laboratory had performed competency assessments on the TP to evaluate their performance as TP, CC, GS, and TS. This was confirmed by the TS during the exit interview.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on procedure manual and quality assurance (QA) review and interview with the technical supervisor (TS), the laboratory did not ensure that proficiency testing (PT) was performed at least twice annually. Findings: 1. The laboratory's PT procedure states that twice a year the laboratory will send 3 patient cases to another pathologist for review. 2. A review of QA records showed that there was no documentation that PT slides had been sent out in 2020. 3. During an interview on 11/19/2021 at 1:00 PM, the TS confirmed that PT slides were not sent out in 2020.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on procedure manual and quality assurance (QA) record review and interview with the technical supervisor (TS), the laboratory did not follow written procedures for performing QA in the laboratory. Findings: 1. The "Mohs Quality Assurance Manual" was reviewed. "Section III. Post-Analytical" states, "Twice a year the Histotechnician, Director of Laboratory Operations, or the Mohs surgeon will review cases previously done. This process will include pulling the patient charts, the Mohs log, and slides. They will be checked to make sure that the operative report, map, Mohs log, and slides are accurate. If there are any discrepancies, it will be noted on the QA form and corrective action will be taken to prevent this from happening again." 2. QA records from 2020 and 2021 were reviewed. There was no documentation that a review of patient cases had been performed in 2020. 3. "Section VI. Quality Control Assessment" states, "The Laboratory Director reviews all quality control charts and logs on at least a monthly basis." There was no documentation that the laboratory director (LD) had reviewed the quality control charts or logs. During an interview at 11:30 AM on the day of the survey, laboratory staff stated that the TS

	reviews everything when they are onsite once a month. 4. "Section IX. Personnel Assessment" states, "The Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance." Record review showed that there was no documentation that the LD had performed competency assessments on the TP to evaluate their performance as TP, CC, GS, and TS. Cross-refer to D5209. 5. "Section XII. Quality Assessment Review with Staff" states, "The Laboratory Director will discuss with the staff, on a quarterly basis, the results of quality assurance reviews and ways in which the laboratory can improve the quality of its work." Laboratory staff stated at 11:30 AM that the LD did not have quarterly QA meetings with the laboratory staff. 6. During an interview on 11/19/2021 at 1:00 PM the TS confirmed that the laboratory did not follow written procedures for performing QA in the laboratory.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical supervisor (TS), the laboratory director (LD) did not ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. The laboratory's PT procedure states that twice a year the laboratory will send 3 patient cases to another pathologist for review. 2. A review of histopathology PT records from 2021 showed that stained histopathology slides from 5 patient cases were sent to another pathologist for review on 5/25/2021. The results of the PT were not reviewed and signed by the LD, showing that the PT had been evaluated. 3. During an interview on 11/19/2021 at 1:00 PM, the TS confirmed that histopathology PT results were not reviewed and signed by the LD.
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: The laboratory director (LD) failed to 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. Cross-refer to D5209.