Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D2138718	**(X3) Date Survey Completed** 05/21/2021
Name of Provider or Supplier Advanced Dermatology Of Michigan	**Street Address, City, State** 416 S Creyts Road Suite A, Lansing, MI	
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**
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 record review and interview with the Mohs Technician, the laboratory failed to assess testing personnel competency for 1 (2019) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of competency assessment for Testing Personnel #1 listed on the CMS-209 form in 2019. 2. A review of the laboratory's "Proficiency Testing Mohs Histopathology" revealed a section stating, "1. Proficiency testing will be performed bi-annually. To be sent out and returned by end of June and Dec. 2. A total of 10 cases will be selected at random for review from cases that include Stages 2-4 or greater. 3. Slides will be sent to Advanced Dermatology Pathology Laboratory and reviewed by a dermatopathologist and/or a designated Advanced Dermatology Mohs surgeon for a blind review for accuracy of diagnostic criteria (positive/negative margins). 4. Slides will also be reviewed for staining quality. 5. Pathology results will be paired with Mohs surgeon results. If Pathologist and Mohs surgeon do not agree , a second Pathologist will be consulted." 3. An interview on 5/21/21 at 10:12 am with the Mohs Technician revealed the laboratory uses their proficiency testing activities for the twice annual verification of accuracy requirements to meet their competency requirements. The Mohs Technician confirmed no competency assessment documentation was present for testing personnel in 2019.
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 record review and interview with the Mohs Technician, the laboratory failed to verify the accuracy of its histopathology testing at least twice annually for 2 (2019 to 2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of verification of accuracy activities at least twice annually for the following years: a. 2019, no documentation available. b. 2020, the second verification of accuracy event was not performed. 2. A review of the laboratory's "Proficiency Testing Mohs Histopathology" revealed a section stating, "1. Proficiency testing will be performed bi-annually. To be sent out and returned by end of June and Dec. 2. A total of 10 cases will be selected at random for review from cases that include Stages 2-4 or greater. 3. Slides will be sent to Advanced Dermatology Pathology Laboratory and reviewed by a dermatopathologist and/or a designated Advanced Dermatology Mohs surgeon for a blind review for accuracy of diagnostic criteria (positive/negative margins). 4. Slides will also be reviewed for staining quality. 5. Pathology results will be paired with Mohs surgeon results. If Pathologist and Mohs surgeon do not agree , a second Pathologist will be consulted." 3. An interview on 5/21/21 at 10:12 am with the Mohs Technician revealed the laboratory did not have documentation of verification of accuracy activities at least twice annually in 2019 and 2020.
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 and interview with the Mohs Technician, the laboratory failed to ensure reagents were labeled with the identity, preparation, and expiration dates for 3 bottles observed. Findings include: 1. An observation of the laboratory on 5/21/21 at 9:06 am made by the surveyor revealed three solutions in plastic containers that were unlabeled. 2. An interview on 5/21/21 at 9:06 am with the Mohs Technician confirmed the three solutions in the plastic containers were not labeled with the identity, preparation, and expiration dates.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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 Mohs Technician, the laboratory failed

	to ensure tissue inks used in gross tissue examinations did not exceed their expiration dates for 8 of 8 tissue inks observed. Findings include: 1. During an observation of the laboratory on 5/21/21 at 9:06 am, the surveyor observed eight containers labeled "Tissue marking Dye". One bottle had an expiration date of 12/1/20 and the other seven had a shared expiration date of 1/1/21. 2. . An interview on 5/21/21 at 9:06 am with the Mohs Technician confirmed the inks were in use for testing after the expiration dates had elapsed.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician, the laboratory failed to ensure it documented the date and time of specimen receipt into the laboratory for 4 (Patients L19-115, L19-133, L19-149, and L19-191) of 10 patient test records reviewed. Findings include: 1. A review of patient test records revealed the following patients had testing performed without the laboratory documenting the time received in the laboratory: a. L19-115, testing performed on 05/10/2019. b. L19-133, testing performed on 06/28/2019. c. L19-149, testing performed on 07/15/2019. d. L19-191, testing performed on 09/12/2019. 2. An interview on 5/21/21 at 10:18 am with the Mohs Technician confirmed the patient test records listed above did not contain the time the specimens were received in the laboratory.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) 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. This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician, the Laboratory Director failed to ensure quality assessment programs were maintained for 7 (August 2019 to May 2021) of 8 quarters reviewed. Findings include: 1. A review of the laboratory's "Mohs Quality Assurance Manual" revealed a section stating, "It is the policy of this laboratory to apply the principles of this QA Program to all activities of this laboratory, including pre-analytic, analytic and post-analytic activities. The QA Program assures the accurate, reliable and prompt reporting of test results and provides methods to evaluate the effectiveness of its policies and procedures, to identify and correct problems, and to assure the adequacy and competency of the staff." and "On a quarterly basis the Histotechnician or Director of Laboratory Operations will review 10 percent of cases done during the previous quarter. This process will include pulling the patient charts, the Mohs log, and slides. They will be check to make sure that the op-report, map, Mohs log and slides are accurate. If there

	are any discrepancies it will be noted on the Quarterly QA form and corrective action will be taken to prevent this from happening again" 2. A review of the laboratory's records revealed a lack of documentation of quality assessment activities performed after August 2019. 3. An interview on 5/21/21 at 10:10 am with the Mohs Technician confirmed the laboratory did not have documentation of quality assessments after August 2019.