Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0362730	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Michigan	36700 Woodward Ave, Suite 203, Bloomfield Hills, 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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with an office staff member, the laboratory failed to retain a copy of the original histopathology Mohs' map for 18 (October 2017 to March 2019) of 18 months performing Mohs' surgeries for at least ten years. Findings include: 1. Lack of records to review revealed the laboratory did not keep the original Mohs' map for as least ten years from the date of reporting. 2. On March 21, 2019 at approximately 1:30 PM when queried, an office staff member stated that once the map is scanned into the electronic medical record (EMR) file the original copy of the map is discarded. 3. During the interview on March 21, 2019 at approximately 1:30 PM, the office staff member acknowledged that the original Mohs' map is not retained after scanning into the EMR system for at least ten years from the date or reporting.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the office manager, the laboratory failed to have a electronic request for patient testing from an authorized person for the mycology testing for one (#10) of 12 patient charts audited. Findings include: 1. Record review revealed for patient chart audit #10 on April 3, 2018, the laboratory did not have an electronic request for the potassium hydroxide (KOH) testing that was performed. 2. During the interview on March 21, 2019 at approximately 1:00 PM, the office manager acknowledged their was no electronic request for the KOH testing in the patient's electronic medical record file.
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 review, record review, and interview with the histology tech, the laboratory failed to follow the written procedure for the "Maintenance of Eyewash Station" for 15 (2018 and January - March 2019) of 24 months reviewed. Findings include: 1. Procedure review for the "Maintenance of Eyewash Station" revealed the eyewash station was to be activated on a weekly basis. 2. Record review of the eyewash station maintenance log revealed there was no documentation of the weekly maintenance for January - December 2018 and January to March 2019. 3. During the interview on March 21, 2019 at approximately 11:15 AM, the histology tech acknowledged she was unaware of the maintenance requirements for the eyewash station.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the histology processing tech, the laboratory failed to document the corrective action taken for humidity readings outside the expected range for three (January, February, and March 2019) of 17 months reviewed from October 2017 to March 2019 for the proper operation of the histology processing equipment. Findings include: 1. Record review of the "Advanced Dermatology Laboratory Temp/Humidity Log" revealed the range on the log was incorrect. 2. Record review of the "Advanced Dermatology Laboratory Temp /Humidity Log" revealed for ten days in January - March 2019 the humidity readings

	were below the expected range of 20-60% as follows: a. January 7, 14, 21, and 28 b. February 4, 18, and 25 c. March 4, 11, and 18 3. During the interview on March 21, 2019 at approximately 10:00 AM, the histology tech confirmed the range was incorrect which lead to the humidity readings being out of range and no corrective action was documented.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to ensure the final mycology results were present in the patient's electronic medical record (EMR) file for two (#10 and #12) of 12 patient charts audited. Findings include: 1. Record review revealed for the patient charts audited that the final KOH result was not entered into the EMR file for two patient's as follows: a. #10 - April 3, 2018 b. #12 - March 19, 2019 2. During the interview on March 21, 2019 at approximately 1:30 PM, the office manager confirmed the final patient results are not monitored for result entry or accuracy in the EMR system.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the histology tech and the Laboratory Director (LD), the laboratory failed to ensure the name change of the facility was located on the Mohs' map for eight (#1 - #9) of eight patient charts reviewed. Findings include: 1. Record review revealed the name of the facility performing and reporting the Mohs' tissue slide examination on the Mohs' map changed in March of 2017. 2. Record review of the scanned Mohs' map into the patients electronic medical record (EMR) file revealed the name of the location performing and reporting the Mohs' tissue slide examination did not match the name of the facility for eight Mohs' maps audited as follows: a. Mohs' report - B17-13 b. Mohs' report - B18-11 c. Mohs' report - B18-56 d. Mohs' report - B18-114 e. Mohs' report - B18-159 f. Mohs' report - B18-

	206 g. Mohs' report - B19-221 h. Mohs' report - B19-247 3. During the interview on March 21, 2019 at approximately 1:30 PM, the LD acknowledged the name of the processing and reporting on the Mohs' map did not match the name change from March 2017.