Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0690144	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Michigan	6100 Newport Rd, Suite 100, Portage, 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 record review and interview with the Office Manager (OM) and the Mohs' Technician (MT), the laboratory failed to retain a scanned copy for 10 years of the original Mohs' map for 9 (November 2018 to present date) of 10 months with the installation of a new Laboratory Information System (LIS). Findings include: 1. Record review for the chart audit revealed for 9 of 10 months the laboratory was not consistently scanning in the entire Mohs' map into the LIS system, only a captured picture shot that did not contain all the pertinent information for the final report. 2. When queried on September 25, 2019 at approximately 12:19 pm, the OM and MT stated that if a picture was captured then the map was not scanned into the LIS. 3. During the interview on September 25, 2019 at 12:19 pm, the OM and MT acknowledged the Mohs' map was not consistently scanned into the LIS, therefore not kept for 10 years from the date of reporting.
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 Office Manager (OM) and the Mohs' technician (MT), the laboratory failed to verify the accuracy of testing for the mycology potassium hydroxide (KOH) at least twice annually for 2 (1st and 2nd 2019) of 7 events reviewed. Findings include: 1. Record review of the final graded proficiency testing reports from the American Proficiency Institute (API) revealed the laboratory failed the 1st and 2nd events for 2019 as follows. a. 1st event 2019 - 50% b. 2nd event 2019 -50 % 2. When queried on September 25, 2019 at approximately 10: 00 am if the laboratory completed further testing or did chart reviews, the surveyor was instructed that no further action was taken. 3. During the interview on September 25, 2019 at approximately 10:00 am, the OM and the MT acknowledged that verification of accuracy was not acceptable for the 1st and 2nd events of 2019 and no further action was taken.
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 lack of documentation and interview with the Office Manager (OM) and the Mohs' Technician (MT), the laboratory failed to provide a test request for the potassium hydroxide (KOH) testing for 1 (#3) of 22 charts reviewed. Findings include: 1. Lack of documentation in the patient's chart failed to show a written request to perform the KOH testing performed on February 5, 2018 for 1 (#3) of 22 charts reviewed. 2. During the interview on September 25, 2019 at 12:00 pm, the OM and MT acknowledged the patient's chart did not contain an order for the KOH testing. ***Repeat Deficiency from the April 13, 2017 survey***
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the Office Manager (OM) and the Mohs' Technician (MT), the laboratory failed to have the final mycology potassium hydroxide (KOH) result maintained as part of the patient's chart or medical record for 1 (#3) of 22 patient charts audited. Findings include: 1. Lack of documentation for 1 (#3) of 22 patient charts audited revealed the final test report for the KOH testing was not maintained in the patient's chart or medical record. 2. During the interview on September 25, 2019 at approximately 12:00 pm, the OM and MT acknowledged the final KOH result was not present in the patient's chart or medical record. ***Repeat Deficiency from the April 13, 2019 survey***
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 Office Manager (OM) and the Mohs' Technician (MT), the laboratory failed to ensure 1) the date of testing, the site, and the tumor type were maintained as part of the final Mohs' map for 4 (#18, #20, #21, and #22) of 22 charts audited and 2) the time of receipt into the laboratory of the tissue specimen was not recorded for 13 (#10 - #22) of 22 patient charts audited. Findings include: 1. Record review for 4 (#18, #20, #21, and #22) of 22 charts audited revealed the final Mohs' map was missing the date of the surgery, the site, and the tumor type. 2. Record review for 13 (#10 - #22) of 22 charts audited revealed the specimen receipt time into the laboratory was not recorded on the Mohs' map. 3. During the interview on September 25, 2019 at 12:45 pm, the OM and MT acknowledged the missing information from the Mohs' map.