Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2138718	07/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Michigan	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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to follow its policy to assess testing personnel competency (Refer to D5209), failed to ensure testing personnel followed the its histopathology testing procedure (Refer to D5401), failed to establish policies to correct identified analytic system problems with histopathology slide quality (Refer to D5791 A), failed to follow its policy to ensure corrective actions were performed (Refer to D5791 B), and failed to issue corrected reports to authorized persons referring patients for mohs micrographic surgery when errors in the histopathology testing were detected (Refer to D5821).
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 Office Manager, the laboratory failed to follow its policy to assess competency for Testing Personnel #1 (TP1) for 7 (December 2021 to July 2022) of 7 months since TP1 had been hired to perform histopathology testing. Findings include: 1. A review of the laboratory's "Competency

	Assessment for Testing Personnel" policy on 7/18/22 revealed a section stating, "Competency Assessment occurs at hire, at six months and then annually and is performed for each test the testing personnel performs." 2. A review of the laboratory's personnel records on 7/18/22 revealed TP1 was hired on 12/13/21 and there was a lack of documentation assessing TP1's competency to perform histopathology testing according to the laboratory's policy. 3. An interview on 7/18/22 at 9:41 am with the Office Manager revealed the laboratory uses its verification of accuracy testing of its histopathology testing to meet the competency requirements and confirmed the most recent verification of accuracy testing event was performed on 12/3/21, prior to Testing Personnel #1's hire date. ***This is a repeated deficiency previously cited at the 5/21/21 recertification survey***
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 record review and interview with the Office Manager, the laboratory failed to ensure testing personnel followed its histopathology testing procedure for 13 (L21-138, L21-14, L21-44, L20-242, L20-316, L20-105, L20-108, L20-42, L20-49, L19-194, L19-222, L19-224, and L19-203) of 41 patients the laboratory identified as positive for tumor or were uninterpretable during its verification of accuracy event dated 6/28/21. Findings include: 1. A review of the laboratory's "Procedure for Mohs Frozen Sections" histopathology procedure on 7/18/22 revealed a section titled "Process" stating, "When a good section is obtained, he/she picks it up on a slide. He /she may make other sections according to need. The frozen section slide can then be stained following the desired method, usually rapid H&E. The stained slides are then examined microscopically by the pathologist/physician. The pathologist/physician will annotate on the patients map weather the specimen is negative or positive for tumor. If the specimen is positive, then another stage is taken until the entire tumor is removed. Each additional stage is annotated on the map. In the event that the tumor involvement expands out side the scope of Dermatology i.e. bones or vascular involvement, the patient will be sent to the appropriate physician for treatment." and a section titled "Quality Assurance" stating, "Quality assurance is provided by the pathologist/physician who reads each stained slide." 2. A review of the laboratory's "Mohs Proficiency" logs documenting verfication of accuracy testing on 7/18/22 revealed 13 (L21-138, L21-14, L21-44, L20-242, L20-316, L20-105, L20-108, L20-42, L20-49, L19-194, L19-222, L19-224, and L19-203) of 41 patients performed by the previously employed testing personnel were positive for tumor or the slides were uninterpretable. 3. An interview on 7/18/22 at 9:41 am with the Office Manager confirmed the verification of accuracy testing by a secondary mohs surgeon showed positive tumor margins or slides were uninterpretable in cases performed by the previously employed testing personnel.
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, record review, and interview with the Office Manager, the laboratory failed to ensure reagents and tissue marking dyes used in histopathology testing did not exceed their expiration dates for 3 ("Define MX", Surgipath Tissue Marking Dye Violet Lot 021621, Cardinal Health Tissue Marking Dye Orange Lot 098077) of 11 reagents and tissue marking dyes observed. Findings include: 1. The surveyor observed 11 reagents and tissue marking dyes in the laboratory on 7/18/22 at 9:05 am and the following had exceeded their expiration date: a. Cardinal Health Tissue Marking Dye Orange Lot 098077 expiration date 4/30/22. b. Surgipath Tissue Marking Dye Violet Lot 021621 expiration date 2/16/22. c. A secondary container labeled "Define MX" with the expiration date of "6/22." 2. A review of the laboratory's "Quality Control Maintenance" policy on 7/18/22 revealed a section stating, "No stain or reagent that is expired will be used and a visual inspection of all reagents (including water) will be done to ensure the integrity of each solution." 3. An interview on 7/18/22 at 9:05 am with the Office Manager confirmed the reagent and tissue marking dyes listed above had exceeded their expiration dates. ***This is a repeated deficiency previously cited at the 5/21/21 recertification survey***
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to evaluate hematoxylin and eosin staining materials for intended reactivity each day of use for 2 (10/31/21 and 7/22/21) of 11 testing dates reviewed. Findings include: 1. A review of the laboratory's "Daily Quality Control Slide" log for 11 patient testing dates on 7/18/22 revealed two dates when hematoxylin and eosin staining materials had not been evaluated: a. 7/22/21, six patients received testing. b. 10/31/22, eight patients received testing. 2. A review of the laboratory's "Quality Control Maintenance" policy on 7/18/22 revealed a section stating, "The first frozen section will be stained as a control for the day and submitted to the physician/pathologist for review. If the pathologist determines the quality of the stain unsatisfactory, the stains and reagents are disposed of and the frozen section and staining process is repeated. The pathologist will initial the stain quality and section completeness for the appropriate day." 3. An interview on 7/18/22 at 10:45 am with the Office Manager confirmed the laboratory had not accessed hematoxylin and eosin staining materials for intended reactivity for the dates listed above.
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 Office Manager, the laboratory failed to document the time of specimen receipt into the laboratory for 11 (L22-208, L22-126 stages one and two, L22-134, L22-009, L22-073, L21-347, L21-293, L21-200 stages one and two, and L21-092) of 13 patient test records reviewed. Findings include: 1. A review of 13 patient test records revealed 11 patient specimens did not have the time received in the laboratory documented for the following mohs micrographic surgery specimens: a. L21-092 b. L21-200, stages one and two. c. L21-293 d. L21-347 e. L22-009 f. L22-073 g. L22-134 h. L22-126, stages one and two. i. L22-208 2. An interview on 7/18/22 at 10:17 am with the Office Manager confirmed the time of specimen receipt in the laboratory had not been documented for the patient specimens listed above. ***This is a repeated deficiency previously cited at the 5/21 /21 recertification survey***
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Office Manager, the laboratory failed to establish policies to correct identified analytic system problems with histopathology slide quality for 7 (L21-274, L21-313, L21-13, L21-112, L20-316, L20-326, and L20-101) of 51 cases reviewed for the laboratory's verification of accuracy events on 6/28/21 and 12/3/21. Findings include: 1. A review of the laboratory's "Mohs Proficiency" logs on 7/18/22 revealed verification of accuracy events dated 6/28/21 and 12/3/21 had assessed a total of 51 cases and the following cases had slide quality problems indicating specimens being thick, dried out, or difficult to read: a. L21-274, the comment "thick" was present. b. L21-313, the comment "diff to read" was present. c. L21-13, the comment "slightly thick" was present. d. L21-112, the comment "desiccated, difficult to read" was present. e. L20-316, the comment "thick, desiccated" was present. f. L20-326, the comment "thick, desiccated" was present. g. L20-101, the comment "thick" was present. 2. A review of the laboratory's "Proficiency Testing Mohs Histopathology" policy on 7/18/22 revealed it did not include a process to correct identified problems with the quality of the slides during the laboratory's verification of accuracy testing process. 3. The surveyor requested corrective action to resolve the slide quality problems identified on 7/18/22 at 9:41 am and it was not made available. 4. An interview on 7/18/22 at 9:41 am with the Office Manager revealed the laboratory did not perform corrective action for the slide quality problems identified during twice annual verification of accuracy events. B. Based on record review and interview with the Office Manager, the laboratory failed to follow its policy to ensure corrective actions were performed for 1

	(Patient L21-138) of 13 patients the laboratory identified during verification of accuracy testing dated 6/28/21 found to have positive margins for Basal Cell Carcinoma (BCC) or were uninterpretable. Findings include: 1. A review of the laboratory's "Mohs Proficiency" logs dated 6/28/21 on 7/18/22 revealed 13 of the 41 patients receiving mohs surgery selected for the verification of accuracy review were found to be positive for Basal Cell Carcinoma (BCC) or the slides were uninterpretable by a secondary mohs surgeon. 2. A review of the laboratory's "Procedure for Mohs Frozen Sections" histopathology procedure on 7/18/22 revealed a section titled "Process" stating, "When a good section is obtained, he/she picks it up on a slide. He/she may make other sections according to need. The frozen section slide can then be stained following the desired method, usually rapid H&E. The stained slides are then examined microscopically by the pathologist/physician. The pathologist/physician will annotate on the patients map weather the specimen is negative or positive for tumor. If the specimen is positive, then another stage is taken until the entire tumor is removed. Each additional stage is annotated on the map." 3. A review of the laboratory's "Proficiency Testing Mohs Histopathology" policy on 7/18 /22 revealed a section stating, "Slides will be sent to the Advanced Dermatology Pathology Laboratory and reviewed by a dermatopathologist and/or a designated Advanced Dermatology Mohs surgeon for a blind review to test for accuracy of diagnostic criteria (positive/negative margins)." and a section stating, "In instances where the second Pathologist does not agree, the claim is submitted to the Quality Assurance Committee (physician based) for evaluation and determination of whether the patient will be notified and asked to come back to the office for consultation and further evaluation." 4. A review of email correspondence on 7/18/22 regarding corrective action for patients identified to have positive margins revealed an email from the Compliance Manager dated 11/15/21 stating, "As suggested by the QAC, the compliance department will monitor patients treated with Mohs surgery by (the previously employed testing personnel) and ensure they are scheduled or have had a skin check follow-up 6 months after their Mohs surgery." 5. A review of the electronic medical records for the 13 patients on 7/19/22 revealed Patient L21-138 had mohs surgery performed on 5/22/21 noting stage II had margins negative for tumor. Patient L21-138 did not have a six-month follow-up appointment documented and had not come back to the office since the 6/1/21 appointment when the sutures from surgery had been removed. 6. An interview on 7/19/22 at 11:23 am with the Office Manager confirmed Patient L21-138 had not been seen for a skin check and no attempts to contact the patient had been 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 site of histopathology specimens collected during mohs surgery were

	accurate on the test report for 1 (L21-200) of 11 patient test records reviewed. Findings include: 1. A review of 11 patient test records on 7/18/22 revealed Patient L21-200 had the site of "Left Central Malar Cheek" listed on both the biopsy report prior to being referred for mohs micrographic surgery and the "Micrographic Surgery Operative Map and Pathology Report." The site of "left cheek" was listed on the laboratory's test report for the mohs surgery procedure in the patient's electronic medical record. 2. An interview on 7/18/22 at 10:30 am with the Office Manager confirmed the patient listed above had an inaccurate specimen site listed on the test report for the histopathology specimens collected during mohs surgery in the patient's electronic medical record.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to issue corrected reports to authorized persons referring patients for mohs micrographic surgery when errors in histopathology testing were detected for 13 (L21-138, L21-14, L21-44, L20-242, L20-316, L20-105, L20-108, L20-42, L20-49, L19-194, L19-222, L19-224, and L19-203) of 41 patients the laboratory identified during its verification of accuracy testing dated 6/28/21. Findings include: 1. A review of the laboratory's verification of accuracy for histopathology testing "Mohs Proficiency" logs dated 6/28/21 on 7/18/22 revealed 13 of 41 patients performed by the previously employed testing personnel indicated to be cleared of tumor were positive for Basal Cell Carcinoma (BCC) or the slides were uninterpretable and may be positive during a review by a secondary mohs surgeon. a. L19-203 had a comment stating, "(+) iBCC stage II" b. L19-224 had a comment stating, "(+) BCC" c. L19-222, had a comment stating, "(+) BCC stage II" d. L19-194 had a comment stating, "Stage III uninterpretable" with a question mark by the positive result. e. L20-42 had a comment stating, "Stage III uninterpretable" with a question mark by the positive result. f. L20-49 had a comment stating, "(+) sBCC" g. L20-105 had a comment stating, "no coverslip, uninterpretable" with a question mark by the positive result. h. L20-108 had a comment stating, "(+) BCC" i. L20-316 had a comment stating, "(+) sBCC" j. L20-343 had a comment stating, "(+) iBCC" k. L21-44 had a comment stating, "(+) BCC" l. L21-14 had a comment stating, "? inflamm vs BCC" with a question mark by the positive result. m. L21-138 had a comment stating, " (+) BCC stage III" 2. A review of the electronic medical records for the patients listed above on 7/19/22 revealed a lack of corrected reports indicating a change in the test results. 3. An interview on 7/19 /22 at 11:17 am with the Office Manager confirmed the laboratory had not issued corrected reports for patients listed above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to issue corrected reports to authorized persons referring patients for mohs micrographic surgery when errors in the histopathology testing were detected (Refer to D6082), failed to ensure testing personnel followed the laboratory's histopathology testing procedure (Refer to D6087), failed to establish policies to correct identified analytic system problems with histopathology slide quality (Refer to D6094 A), failed to follow its policy to ensure corrective actions were performed (Refer to D6094 B), and failed to ensure all testing personnel demonstrated accurate performance of histopathology testing prior to testing patients (Refer to D6102).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the Laboratory Director failed to issue corrected reports to authorized persons referring patients for mohs micrographic surgery when errors in histopathology testing were detected. Refer to D5821.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the Laboratory Director failed to ensure testing personnel followed the laboratory's histopathology testing procedure. Refer to D5401.
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: A. Based on record review and interviews, the Laboratory Director failed to establish policies to correct identified analytic system problems with histopathology slide

	quality. Refer to D5791 A. B. Based on record review and interviews, the Laboratory Director failed to follow the laboratory's policy to ensure corrective actions were performed. Refer to D5791 B. ***This is a repeated deficiency previously cited at the 5/21/21 recertification survey***
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the Laboratory Director failed to ensure testing personnel demonstrated accurate performance of histopathology testing prior to testing patients. Refer to D5209.