Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2219579	11/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dmc Dermatology & Mohs, Llc	4715 E Camp Lowell, Tucson, AZ	

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
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 lack of accuracy verification documentation for Frozen Biopsy testing and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2022. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Frozen Biopsy testing at least twice annually during 2022. 2. The LD interviewed on 11/08/2023 at 2:20 PM confirmed that the laboratory failed to verify the accuracy of Frozen Biopsy testing at least twice annually during 2022. 3. The laboratory began testing for Frozen Biopsies on 02/25/2022 and performed 2 tests in 2022.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures for Dermatopathology testing

	and interview with the laboratory director (LD), the laboratory failed to establish written policies and procedures for specimen/slide labeling of Frozen Biopsies and failed to follow established policies and procedures for labeling Mohs slides. Findings include: 1. The laboratory began patient testing in the subspecialty of Histopathology on 05/28/2021, with an annual test volume of 1,000. The laboratory reads and interprets slides in conjunction with Mohs and Frozen Biopsy testing. 2. The laboratory failed to establish written policies and procedures for labeling slides for Frozen Biopsy testing. 3. The LD interviewed on 11/08/2023 at 2:10 PM confirmed the laboratory failed to establish written policies and procedures for labeling slides for Frozen Biopsy testing. 4. The laboratory's established Mohs procedure reviewed during the survey states, "Slides will be marked with 2 patient identifiers of the initials of the patient and the accession number of the Mohs case assigned to the patient." 5. The laboratory failed to include the patient's initials on the slide label for one out of four Mohs cases reviewed during the survey (case# M21-15). 6. The LD interviewed on 11/08/2023 at 1:55 PM confirmed the laboratory failed to follow established slide labeling procedures for Mohs, as evidenced above.
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 lack of written test procedures for review and interview with the laboratory director (LD), the laboratory failed to establish a written test procedure for Frozen Biopsy testing. Findings include: 1. The laboratory began patient testing on 05/28 /2021 in the subspecialty of Histopathology, with an annual test volume of 1,000. The laboratory reads and interprets slides in conjunction with Mohs and Frozen Biopsy testing. 2. No documentation was presented for review during the survey conducted on 11/08/2023 to indicate the laboratory established a written test procedure for Frozen Biopsy testing. 3. The laboratory performed 4 Frozen Biopsies from 05/28 /2021 through 11/08/2023. 4. The LD interviewed on 11/8/2023 at 1:50 PM confirmed the laboratory failed to establish a written test procedure for Frozen Biopsy testing.
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 lack of Quality Control (QC) documentation and interview with the laboratory director (LD), the laboratory failed to document the acceptability of the Hematoxylin & Eosin (H&E) staining materials each day of use for intended reactivity to ensure predictable staining characteristics. Findings include: 1. The

	laboratory began patient testing in the subspecialty of Histopathology on 05/28/2021, with an annual test volume of 1,000. The laboratory reads and interprets slides in conjunction with Mohs and Frozen Biopsy testing. 2. The laboratory performs the Hematoxylin and Eosin (H&E) stain on each specimen prior to the microscopic interpretation. 3. No documentation of the H&E stain acceptability was presented for review for testing that occurred during 2021, 2022 and 2023 through the date of the survey conducted on 11/08/23. 4. The LD interviewed on 11/08/2023 at 2:15 PM confirmed the laboratory failed to document the H&E stain acceptability for intended reactivity to ensure predictable staining characteristics for the timeframe listed above.
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 review of patient test results maintained in the Electronic Health Record (EHR) and interview with the laboratory director (LD), the laboratory failed to have a system in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (entered manually) to final report destination, in a timely manner. Findings include: 1. Patient-specific data and the final test result information for Mohs and Frozen Biopsy testing is manually transcribed by laboratory personnel into the patient's EHR. 2. No documentation was presented for review during the survey conducted on 11/8/2023 to indicate the laboratory has a system in place to ensure the accuracy of patient-specific data and patient test results that are manually entered into the EMR. 3. The LD interviewed on 11/08/2023 at 2:40 PM confirmed the laboratory failed to have a system in place to verify the accuracy of patient-specific data and patient test results that are manually entered into the EMR.
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 review of the laboratory's pathology test reports for Frozen Biopsy interpretations and interview with the laboratory director (LD), the laboratory failed to

	include the gross description on one out of one pathology reports reviewed during the survey. Findings include: 1. On 2/25/2022, the laboratory began testing for Frozen Biopsy interpretations under the subspecialty of Histopathology with an approximate annual test volume of 4. 2. One out of one pathology test reports reviewed during the survey (Case# 356 performed on 6/7/23) failed to include the gross description of the tissue. 3. The LD interviewed on 11/08/2023 at 1:45 PM confirmed the Frozen Biopsy pathology report indicated above failed to include the gross description of the tissue.