Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2185277	05/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Derm Institute Of West Michigan, Plc The	1661 Crystal Springs Blvd Se, Caledonia, 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
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 Practice Manager (PM), the laboratory failed to 1) record the specimen time of receipt into the laboratory for the Mohs' tissue specimens for 3 (#1, #3, and #4) of 5 final Mohs' maps reviewed and 2) the identity of the Mohs' surgeon was not recorded on the Mohs' map for 5 (#1 - #5) of 5 final Mohs' maps reviewed. Findings include: 1. A record review for 3 (#1, #3, and #4) of 5 final Mohs' maps reviewed in the patients electronic medical record (EMR) system revealed the laboratory did not record the specimen time of receipt into the laboratory for the Mohs' tissue specimen on the Mohs' map as follows: a. specimen #1 - no time recorded on the Mohs' map for section II b. specimen #3 - no time recorded on the Mohs' map for section I and II c. specimen #4 - no time recorded on the Mohs' map for section I and II 2. A record review for 5 (#1 - #5) of 5 Mohs' maps reviewed revealed the identity of the Mohs' surgeon was not recorded on the Mohs' map. 3. An interview on 5/10/2021 at 11:00 am, the PM confirmed the above listed were not documented on the final Mohs' map.
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 Practice Manager (PM), the laboratory failed to ensure the name and address of the laboratory where the Mohs' tissue microscopic examinations were performed was on the final Mohs' map for 5 (#1 - #5) of 5 patient Mohs' maps reviewed. Findings include: 1. A record review for 5 (#1 - #5) of 5 patient Mohs' maps reviewed revealed the name and address of the laboratory performing the Mohs' tissue microscopic examinations was not recorded on the Mohs' map. 2. An interview on 5/10/2021 at 11:00 am, the PM confirmed the Mohs' map did not list the name and address of the laboratory performing the Mohs' microscopic tissue examination.
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 with the Practice Manager, the laboratory failed to employ a qualified Laboratory Director that met the qualification requirements of 493.1443 of this subpart. Findings include: 1. The laboratory failed to employ a Laboratory Director that met the qualification requirements for high complexity testing. Refer to D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at

	least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: . Based on record review and interview with the Practice Manager (PM), the laboratory failed to employ a laboratory director that met the qualification requirements for high complexity testing for 5 (January to May 2021) of 5 months the laboratory has been performing Mohs' surgery. Findings include: 1. A record review of Laboratory Director's personnel record revealed a lack of documentation of the following: a. Board certification in anatomic or clinical pathology; or b. Documentation of at least one year of laboratory training during medical residency; or c. Documentation of at least 2 years of experience directing or supervising high complexity testing. 2. A interview on 5/10/2021 at 11:20 am, the PM was unable to provide the surveyor documentation to qualify the Laboratory Director for high complexity testing. 3. The laboratory was provided 7 days after the survey to supply documentation and it was not made available.