Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2191022	03/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Derm Institute Of Chicago	737 N Michigan Ave - Ste 720, Chicago, IL	

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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the laboratory failed to establish written policies and procedures to assess the competencies of four of four testing personnel (TP) performing high complexity tissue grossing (See D5209), failed to perform bi-annual method accuracy verifications twice a year for frozen section biopsy testing (See D5217), and failed to evaluate results of Mohs bi-annual method accuracy (See D5221) in the subspecialty of histopathology in 2023 and 2024.
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 review of the CMS-209 (Laboratory Personnel) Form, laboratory policies

	and procedures, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the laboratory failed to establish written policies and procedures to assess the competencies of four of four testing personnel (TP) performing high complexity tissue grossing in the subspecialty of histopathology in 2023 and 2024. Findings include: 1. Review of the CMS-209 (Laboratory Personnel) Form identified four TP (TP: 3, 5, 6, and 7) performing high complexity tissue grossing in 2023 and 2024. 2. Review of the laboratory policies and procedures identified the laboratory failed to have a competency assessment procedure in place for tissue grossing TP in the subspecialty of histopathology. 3. Interviews with the LD and laboratory representative on 03/03/2025, at 1:17 pm, confirmed that the laboratory failed to have a competency procedure in place for high complexity tissue grossing TP.
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 review of laboratory records, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the laboratory failed to perform bi-annual method accuracy verifications (proficiency testing/peer reviewed histopathology interpretations) twice a year for frozen section biopsy testing in the subspecialty of histopathology from the beginning of 2023 through the date of survey, 03/03/2025, affecting four patient test results. Findings include: 1. Review of laboratory records revealed no documentation of bi-annual method accuracy verifications for histopathology frozen section biopsies tested from the beginning of 2023 through the date of survey, 03/03/2025, affecting four patients. Date: Biopsy #: 06/20/2023 23-055 12/06/2023 23-128 01/16/2024 24-010 04/16/2024 24-065 2. Interviews with the LD and laboratory representative on 03/03/2025, at 2:55 pm, confirmed the laboratory failed to perform bi-annual method accuracy verifications twice a year for frozen section biopsy testing from the beginning of 2023 through the date of survey, 03/03/2025, affecting four patient test results.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interviews with the laboratory director (LD) and the laboratory representative, the laboratory failed to evaluate results of Mohs bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for four of four events from the beginning of 2023 to the date of survey, 03/03/2025. Findings include: 1. Review of laboratory records revealed a lack of documentation of evaluations of results upon receipt of peer reviewed Mohs histopathology interpretations for four of four reviewed bi-annual method accuracy events. 2. Interviews with the LD and laboratory representative on 03

	/03/2025, at 2:55 pm, confirmed the laboratory failed to evaluate results of bi-annual method accuracy for four of four events from the beginning of 2023 to the date of survey, 03/03/2025.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the laboratory failed to have a policy/procedure in place for frozen section biopsy testing in the subspecialty of histopathology, affecting four patients. Findings include: 1. Review of laboratory records revealed the laboratory had performed four frozen section biopsies in the subspecialty of histopathology in 2023 and 2024. Date: Biopsy #: 06/20/2023 23-055 12/06/2023 23-128 01/16/2024 24-010 04/16/2024 24-065 2. Review of laboratory policies and procedures revealed the lack of a policy/procedure in place for frozen section biopsy testing in the subspecialty of histopathology. 3. Interviews with the LD and laboratory representative on 03/03 /2025, at 2:55 pm, confirmed the laboratory failed to have a policy/procedure in place for frozen section biopsy testing in the subspecialty of histopathology, affecting four patients.
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 review of the CMS-209 (Laboratory Personnel) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the LD failed to ensure one of two testing personnel performing Mohs histopathology interpretations was competent to perform the testing prior to reporting patient results, affecting 93 patients (See D6079), and failed to ensure Mohs quality assurance assessments (bi-annual method accuracy/proficiency testing/peer reviewed histopathology interpretations) were performed as stated for four of four events (See D6093).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory

	director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the LD failed to ensure one of two testing personnel (TP) performing Mohs histopathology interpretations was competent to perform the testing prior to reporting patient results, affecting 93 patients. Findings include: 1. Review of the CMS-209 (Laboratory Personnel) Form identified two TP (TP: 1 and 2) performing Mohs histopathology interpretations. 2. Review of laboratory records revealed TP #2 had reported 93 patient results from 04 /02/2024 through the date of survey, 03/03/2025. Date: # of patients resulted: 04/02 /2024 8 05/07/2024 10 08/20/2024 10 10/15/2024 11 10/31/2024 9 11/19/2024 11 12 /05/2024 7 12/31/2024 10 01/21/2025 9 02/18/2025 8 3. Review of laboratory policies and procedures revealed the policy titled, "Quality Assurance Program", which stated, under "Verification of Test Accuracy", "This laboratory verifies the overall accuracy of Mohs testing by participating in reciprocal reading between the Mohs surgeons within the practice for the required Mohs Surgery ...Peer Review." 4. Review of laboratory records revealed a lack of bi-annual peer reviewed histopathology interpretations for TP #2. 5. Interviews with the LD and laboratory representative on 03/03/2025, at 2:55 pm, confirmed the LD failed to ensure one of two TP performing Mohs histopathology interpretations was competent to perform the testing prior to reporting patient results, affecting 93 patients.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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: Based on review of laboratory records, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the laboratory director failed to ensure Mohs quality assurance assessments (bi-annual method accuracy/proficiency testing/peer reviewed histopathology interpretations) were performed as stated for four of four events from the beginning of 2023 to the date of survey, 03/03/2025. Findings include: 1. Review of laboratory records revealed the form titled, "Mohs Case Quality Assurance Form", which stated, "For Quality Assurance purposes, a minimum of 2 cases are reviewed by [Testing Personnel #1], MD, or [Testing Personnel #2], MD, a qualified Mohs Surgeon or Dermatopathologist for accuracy and completeness." 2. Review of laboratory records, including that of Mohs bi-annual peer reviewed histopathology interpretations, revealed only one peer reviewed histopathology case was bi-annually peer reviewed in the years of 2023 and 2024. Date: # of Cases: 06/20/2023 1 12/19/2023 1 02/06/2024 1 05/21/2024 1 3. Interviews with the LD and laboratory representative on 03/03/2025, at 2:55 pm, confirmed the

	LD failed to ensure Mohs quality assurance assessments (bi-annual method accuracy /proficiency testing/peer reviewed histopathology interpretations) were performed as stated for four of four events from the beginning of 2023 to the date of survey, 03/03 /2025.