Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2083635	11/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Illinois Dermatology Institute	25 E Washington St Suite #1221, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interviews with the laboratory representative (LR); the laboratory failed to ensure three of four Mohs surgical maps were retained for two years post Mohs micrographic surgery date (See D3031) and failed to retain all histopathology slides for ten years post Mohs micrographic surgery date for one of four patients reviewed in the subspecialty of histopathology (See D3043).
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to retain Mohs surgical maps for three of four Mohs micrographic surgical patient reports reviewed in the subspecialty of histopathology. Findings include: 1. Review of patient test reports revealed a lack

	of documentation of Mohs micrographic surgical maps for three of four patient reports reviewed. Test Date Patient Identifier/ Case # 10/18/2023 MM0000062770/ 23-77 11 /08/2023 352004.0-1/ 23-87 09/25/2024 MM0000132780/ 24-52 2. Interview with the LR on 11/12/2025, at 3:28 pm, confirmed the laboratory failed to retain Mohs surgical maps for three of four Mohs surgical patient reports reviewed in the subspecialty of histopathology.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) (a)(7) Slide, block, and tissue retention-- (a)(7)(i) Slides. (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). (a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination. (a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory representative (LR); the laboratory failed to retain all histopathology slides for ten years from the date of the Mohs micrographic surgery histopathologic examination for one of four patients reviewed. Findings include: 1. Review of the patient log for Mohs micrographic surgery histopathologic examination indicated a total of one slide was created for the following patient. Date: Case/ Accession #: # of slides: 10/18/2023 23-77/ MM0000062770 1 2. The laboratory failed to provide one of one patient slides for Case #23-77. 3. Interview with the LR on 11/12/2025, at 3:28 pm, confirmed the laboratory failed to retain all histopathology slides for ten years from the date of the Mohs micrographic surgery histopathologic examination for one of four patients reviewed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to ensure microscopic potassium hydroxide (KOH) PT results were evaluated upon receipt for the years 2023 through 2025. Findings Include: 1. Review of the API PT records for 2023 through 2025 revealed the laboratory failed to document review of KOH PT results for five of eight event results upon receipt. Event (E#) Year Results Reviewed: E3 2023 No E1 2024 No E3 2024 No E1 2025 No E2 2025 No 2. Interview with the LR on 11/12/2025, at 3:28 pm confirmed the laboratory failed to ensure microscopic KOH PT results were evaluated for the years 2023 through 2025.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory representative (LR); the laboratory failed to establish procedures for two of three tests performed (See D5401), failed to have an alternative control procedure in place for two of three tests performed, microscopic potassium hydroxide (KOH) wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology (See D5485), and failed to follow written policies and procedures for monitoring, assessing, and correcting identified problems for four of eight quarters in the subspecialty of histopathology from 2023 through the date of survey, 11/12/2025 (See D5791).
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, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to establish procedures for two of three tests performed, microscopic potassium hydroxide (KOH) wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology. Findings include: 1. Review of laboratory policies and procedures revealed the laboratory failed to have a procedure in place for: a. Microscopic KOH wet mount testing in the subspecialty of mycology, b. Microscopic scabies wet mount testing in the subspecialty of parasitology. 2. Interview with the LR on 11/12/2025, at 1:15 pm, confirmed the laboratory failed to have a procedure for microscopic KOH in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) (h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. (a) The laboratory must check the following for positive and negative reactivity using control organisms: This STANDARD is not met as evidenced by:

	Based on review of the laboratory policies and procedures, laboratory records, quality control (QC) records, random sampling of patient results, and interview with the laboratory representative (LR); the laboratory failed to have an alternative control procedure in place for two of three tests performed, microscopic potassium hydroxide (KOH) wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology, affecting 58 patients. Findings include: 1. Review of laboratory procedures revealed a of lack KOH and scabies testing procedures, including defined alternative control procedures (See D5401). 2. Review of laboratory policies and procedures revealed the document titled, "Job Descriptions for Laboratories performing tests of High Complexity (HC) - Laboratory Director" which states in point 5, "Ensure the quality control and quality assurance programs are established and maintained to assure the quality of the laboratory services provided and to identify failures in quality as they occur." 3. Review of four of four patient test results for KOH and scabies wet mount testing found no documented alternative controls. Date: Patient Identification: 02/02/2024 MM0000105289 07/08/2024 MM0000132532 01/21/2025 MM0000151365 07/21 /2025 MM0000174022 4. Review of laboratory records revealed the form titled "KOH results" with 58 patient results logged from 02/05/2024 through the date of survey, 11/12/2025. 5. Interview with the LR on 11/12/2025, at 3:28 pm, confirmed the laboratory failed to have an alternative control procedure in place for two of three tests performed, microscopic potassium hydroxide (KOH) wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology, affecting 58 patients.
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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for four of eight quarters in the subspecialty of histopathology from 2023 through the date of survey, 11/12/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Quality Assessment [QA] of Fact", which stated, "The following statements of fact will be assessed quarterly and documented as the laboratory's QA minutes. "Statements of fact to be assessed: 1. Confidentiality 2. Specimen ID/ Integrity 3. Complaints 4. Communications 5. Personnel Competency 6. Proficiency testing 7. General Lab Systems Assessment 8. Test Request 9. Written Info 10. Unsatisfactory Specimen 11. QC 12. Reported Data" 2. Review of laboratory records revealed a lack of documentation of quarterly quality assurance checks performed for the four of eight quarters from 2023 through the date of survey 11/12/2025. Year: Quarter (Q): QA Performed: 2023 Q3 No 2025 Q1 No 2025 Q2 No 2025 Q3 No 3. Interview with the LR on 11/12/2025, at 3:28 pm, confirmed the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for four of eight quarters in the subspecialty of histopathology from 2023 through the date of survey, 11/12/2025.

D5801	TEST REPORT CFR(s): 493.1291(a) (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: A. Based on review of laboratory records, lack of documentation, and interviews with the laboratory representative (LR); the laboratory failed to establish and maintain a system to differentiate patients tested for microscopic potassium hydroxide (KOH) wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology between 02/05/2024 and the date of survey, 11/12/2025, affecting 58 patients. Findings Include: 1. Review of laboratory records revealed the form titled "KOH results" with 58 patient results logged from 02/05/2024 through the date of survey, 11/12/2025. 2. Interview with the LR on 11/12/2025, at 1: 15 pm, revealed the above-mentioned log was used to document both KOH and scabies test results. 3. Interview with the LR on 11/12/2025, at 3:28 pm, confirmed the laboratory failed to maintain a system to establish and maintain a system to differentiate patients tested for KOH wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology between 02/05/2024 and the date of survey, 11/12/2025, affecting 58 patients. B. Based on review of laboratory records and interview with the laboratory representative (LR); the laboratory failed to ensure patient-specific data and test results were transferred accurately to final reports for one of four Mohs micrographic surgery reports reviewed in the subspecialty of histopathology. Findings Include: 1. Review of laboratory records revealed the document titled, "Mohs Surgery Log", which indicated, a. Patient 352004.0-1 b. Case number 23-87, c. Tested on 11/08 /2023, d. Number of stages: Two stages (II) 2. Review of the patient test report for patient 352004.0-1 with case number 23-87, tested on 11/08/2023, revealed, under "Mohs Operative Note", ..."Number of Stages: 3". 3. Interview with the LR on 11/12 /2025, at 11:21 am, confirmed the laboratory failed to have to ensure patient-specific data and test results were transferred accurately to final reports for one of four Mohs micrographic surgery reports reviewed in the subspecialty of histopathology.
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 laboratory policies and procedures, proficiency testing (PT) records, laboratory records, lack of documentation, and interviews with the laboratory representative; the laboratory failed to ensure microscopic potassium hydroxide

	(KOH) PT results were evaluated upon receipt for the years 2023 through 2025 (See D6091), failed to ensure an alternative control procedure was in place for two of three tests performed, KOH wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology (See D6093), failed to ensure written policies and procedures for monitoring, assessing, and correcting identified problems were follow for four of eight quarters in the subspecialty of histopathology (See D6094), and failed to ensure procedures were established for two of three tests performed, KOH wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology (See D6106).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure microscopic potassium hydroxide PT results were evaluated upon receipt for the years 2023 through 2025 (See D5211).
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 the laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure an alternative control procedure in place for two of three tests performed, microscopic potassium hydroxide wet mount testing in the subspecialty of mycology and microscopic scabies wet mount testing in the subspecialty of parasitology, affecting 58 patients (See D5485) and failed to ensure written policies and procedures for monitoring, assessing, and correcting identified problems were followed for four of eight quarters in the subspecialty of histopathology from 2023 through the date of survey, 11/12/2025 (See D5791).
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure

	procedures were established for two of three tests performed, microscopic potassium hydroxide wet mount testing and microscopic scabies wet mount testing in the specialty of microbiology (See D5401).
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, the CMS-209 (Laboratory Personnel Report), laboratory records, lack of documentation, and interview with the laboratory representative (LR); the technical supervisor (TS) failed to evaluate competency assessments for two of two testing personnel (TP) annually for microscopic scabies wet mount testing in the subspecialty of parasitology from the last quarter of 2023 through the date of survey, 11/12/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Competency Assessment Policy", which stated, "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples is performed ... on a quarterly basis". 2. Review of the CMS-209 (Laboratory Personnel Report) revealed two TP (TP: A & B) performed microscopic scabies wet mount testing. 3. Review of laboratory competency evaluation records revealed no competency evaluations were performed by the TS, as identified on the CMS-209,for two of two TP (TP: A & B) for microscopic scabies testing between the last quarter of 2023 through the date of survey, 11/12/2025. TP Evaluation Date: A Oct-Dec 10/27/2023 A Jan-Mar 02/05/2024 A Apr-Jun 04/08/2024 A Jul-Sep (no date provided) A Oct-Dec 10/30/2024 B Oct-Dec 10/10/2023 B Jan-Mar 02/20/2024 B Apr-Jun 05/13/2024 B Jul-Sep (no date provided) B Oct-Dec 10/04/2024 4. Interview with the LR on 11/12/2025, at 2:01 pm, confirmed the TS failed to evaluate competency assessments for two of two TP performing scabies testing in the laboratory from the last quarter of 2023 through the date of survey, 11/12/2025.