

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2090082	(X3) Date Survey Completed 05/28/2026
Name of Provider or Supplier Lakeside Dermatology, A Forefront Derm Practice	Street Address, City, State 1425 Club Hunt Rd, Ste 202, Gurnee, 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
D0000	A recertification survey was conducted on 05/28/2026. The laboratory was found to be out of compliance with the CLIA regulations (42 CFR Part 493) for the following condition-level deficiencies: D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor;
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. 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 (LR); the laboratory procedure "KOH Examination and QC" failed to include control procedures for Potassium Hydroxide (KOH) preparations. Findings include: 1. Review of laboratory policies and procedures revealed the document titled, "Job Descriptions for Laboratories performing tests of High Complexity - Laboratory Director" which stated 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 2. Review of the laboratory procedure titled, "KOH Examination and QC", failed to define the type of control used and criteria of acceptable control results. 3. Interview with LR on 05/28/2026, at 11:08 am, confirmed the laboratory procedure "KOH Examination and QC" failed to include control procedures for Potassium Hydroxide (KOH) preparations.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and interview with laboratory representatives (LR); the laboratory failed to ensure seven of seven policies and procedures in the specialty of pathology were approved via signature and date by the current laboratory director (LD). Findings include: 1. Review of laboratory policies and procedures revealed a policy titled, "Lab Director Responsibilities" which stated, "(e) The laboratory director must-(14) Ensure that an approved procedure manual is available. to all personnel responsible for any aspect of the testing process;" 2. Review of laboratory policies and procedures revealed no signature and date, by the current LD for seven of seven dermatopathology policies and procedures reviewed Policy /Procedure Name: M-721-C-i Proficiency Testing M-733 Quality Assessment Program-PPM/Laboratory M-733-i Quality Assessment Program- MOHS Laboratory M-735-B-i Personnel Competency Testing M-737-i KOH Examination and QC M-737-ii Ectoparasite/ Wet Mount Examination M-815 Pathology Specimen Collection and Handling 3. Interview with the LR on 05/28 /2026, at 3:37 pm, confirmed the laboratory failed to ensure seven of seven policies and procedures in the specialty of pathology were approved via signature and date by the current LD.
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, random sampling of patient results, quality control (QC) records, laboratory records, lack of documentation and interview with the laboratory representative (LR); the laboratory

	failed to document alternative control procedures to detect immediate errors and monitor test performance over time for microscopic potassium hydroxide (KOH) wet mount testing for four of four patient testing dates reviewed. The laboratory reported KOH wet mount testing results for 63 patients between January of 2024 through May of 2026. Findings include: 1. The laboratory failed to establish quality control procedures for Potassium Hydroxide (KOH) preparations in the specialty of microbiology (See D5403). 2. Four of four patient test results reviewed for KOH wet mount testing lacked alternative quality control documentation. Date: Patient Identification: 03/05/2024 7842056 04/12/2024 7898437 05/16/2024 8745186 03/11/2026 3476488 3. Review of laboratory records revealed the Excel sheet titled "Forefront Charges" for KOH testing with 63 patient results logged from 01/17/2024 through 05/20/2026. 4. Interview with the LR on 05/28/2026, at 11:08 am, confirmed the laboratory failed to document alternative control procedures to detect immediate errors and monitor test performance over time for microscopic potassium hydroxide (KOH) wet mount testing for four of four patient testing dates reviewed.
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, laboratory records, lack of documentation, and interview with the laboratory representative (LR); the laboratory director (LD) failed to review results of biannual method accuracy (proficiency testing /peer reviewed histopathology interpretations) for four of five dermatopathology Mohs Micrographic surgical slide peer reviewed events (See D6091). The LD also failed to ensure seven of the seven policies and procedures reviewed were approved and available for aspects of histopathology testing (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 laboratory's performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with laboratory representatives (LR); the laboratory director (LD) failed to review results of biannual method accuracy (proficiency testing /peer reviewed histopathology interpretations) for four of five dermatopathology Mohs Micrographic surgical slide peer reviewed events performed in 2024, 2025 and 2026. Findings include: 1. Review of laboratory policies and procedures revealed a policy titled the "Lab Director Responsibilities" worksheet revealed, which stated, "(e) The laboratory director must-(4) (iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action:" 2. Review of laboratory policies and procedures revealed a procedure titled, "Proficiency Testing" for "Frozen section

	and Mohs Micrographic Surgery Slides" which stated, "The Mohs surgeon will review the log after the review. If additional comments require additional intervention the Mohs surgeon will address as required." 3. Review of laboratory records revealed a lack of documented review of results for four of five biannual method accuracy peer reviewed Mohs Micrographic surgical slide interpretations events in 2024 through 2026. Date(s) of testing: Date of review: January 2026 05/11/2026 April/May 2025 06/11/2025 November 2024 12/09/2024 February/March 2024 08/05/2024 4. Interview with LR on 05/28/2026, at 10:30am, confirmed the LD failed to review results of biannual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for four of five dermatopathology Mohs Micrographic surgical slide peer reviewed events performed in 2024, 2025 and 2026.
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, laboratory records, lack of documentation, and interview with laboratory representative (LR); the laboratory director (LD) failed to ensure seven of the seven policies and procedures were approved and available for the specialty of pathology testing (See D5407).
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, CMS-209 (Laboratory Personnel Report), patient test results, and interview with the laboratory representative (LR); the technical supervisor (TS) failed to ensure quality control programs were established and maintained to ensure the quality of laboratory services provided (See D6117). The TS also failed to ensure that site specific competency was established and maintained for eight of eight testing personnel to perform high complexity grossing procedures for the subspecialty of dermatopathology annually after the first year of patient specimen testing (See D6120).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, patient test reports, lack of documentation, and interview with laboratory representative (LR); the technical supervisor (TS) failed to ensure quality control programs were maintained to ensure the quality of laboratory services provided (See D5485).
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, CMS-209 (Laboratory Personnel Report), personnel records, random sampling of patient results and interview with laboratory representatives (LR); the technical supervisor (TS) failed to ensure competency was evaluated and maintained for eight of eight testing personnel (TP) performing histopathology tissue grossing in the years 2024 through the date of survey, 05/28/2026. Findings include: 1. Review of the laboratory policies and procedures revealed a document titled "Technical Supervisor Responsibilities" which stated, "(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" "(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semi-annually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology changes ..." 2. Review of the CMS-209 (Laboratory Personnel Form) revealed eight TP (TP 4, through 11) performing high complexity grossing of Mohs tissue specimens. 3. Review of the testing personnel records revealed the lack of competency assessments performed for eight of eight TP performing the grossing aspect of Mohs tissue specimens by the laboratory 4. Interview with the laboratory representative on 05/28 /2026, at 9:10 am, confirmed the technical supervisor (TS) failed to ensure competency was evaluated and maintained for eight of eight testing personnel (TP) performing histopathology tissue grossing in the years 2024 through the date of survey, 05/28/2026.