Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2308467	09/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Lighthouse Dermatology & Skin Cancer Specialists	26901 Harper, Saint Clair Shores, 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
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 record review and interview with the laboratory director (LD), the laboratory failed to implement the competency assessment policy for 15 (May 2025 - September 2026) of 15 months. Findings include: 1. A review of the laboratory's policies and procedures revealed that a competency assessment policy was not included. 2. During an interview on September 11, 2026, at 12:45 PM, the surveyor requested the competency assessment policy and none was provided. The LD confirmed that the competency assessment policy was not available. ***This is a repeat deficiency from 5/29/2025.***
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory director (LD), the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess general laboratory systems for 15 (May 2025 -

	September 2026) of 15 months reviewed. Findings include: 1. A review of the laboratory's quality assessment documentation revealed that written policies and procedures describing the ongoing mechanism used to monitor, assess, and, when indicated, correct problems identified through the laboratory's general laboratory systems quality monitors were not available. 2. A review of the Laboratory Director Quarterly Checklist for QA revealed that the laboratory had not established written procedures describing how identified quality problems would be evaluated, corrected, and reassessed for effectiveness. 3. During an interview on September 11, 2026, at 12: 45 PM, the surveyor requested the laboratory's written Quality Assessment policy and procedures. The LD confirmed that the requested documentation was not available.
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 record review and interview with the laboratory director (LD), the laboratory failed to ensure the procedure manual contained complete written instructions for applicable elements of the Mohs histopathology testing procedure for 15 (May 2025 - September 2026) of 15 months. Findings include: 1. A review of the laboratory's Mohs procedure revealed that the procedure manual did not include complete written instructions for: a. Slide labeling. b. Slide storage and retention. c. Specimen acceptance and rejection criteria. 2. During an interview on September 11, 2026, at 12:45 PM, the surveyor requested the missing written procedures. The LD confirmed that the requested documentation was not available.
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 record review and interview with the laboratory director (LD), the laboratory failed to ensure the current procedure manual was approved, signed, and dated before use for 15 (May 2025 - September 2026) of 15 months. Findings include 1. A review of the laboratory's procedure manual revealed that the procedures did not contain documentation of approval, signature, and date before use. 2. During an interview on September 11, 2026, at 12:45 PM, the surveyor requested documentation demonstrating that procedures had been approved, signed, and dated by the LD before use. The LD confirmed that the requested documentation was not available.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory director (LD), the laboratory failed to establish written corrective action policies and procedures for 15 (May 2025 - September 2026) of 15 months. Findings include: 1. A review of the laboratory's corrective action documentation revealed that a written corrective action policy and procedure was not present. 2. During an interview on September 11, 2026, at 12:45 PM, the surveyor requested the laboratory's written corrective action policy and procedure. The LD confirmed that the requested documentation was not available.