

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2329300	(X3) Date Survey Completed 01/13/2026
Name of Provider or Supplier Legacy Dermatology Group	Street Address, City, State 2817 S Milford Road Suite 101, Highland, 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
D0000	A recertification survey was performed on January 13, 2026 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiencies: 493.1219 Condition: Histopathology. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to follow its quality assessment policy (refer to D5391), failed to include the laboratory's process for using the Histopro 414 linear stainer (refer to D5403), failed to use procedures approved, signed, and dated by the laboratory director prior to use (refer to D5407), failed to establish performance specifications for its Mohs surgery histopathology testing prior to patient testing (refer to D5423), failed to perform weekly maintenance for its Dakewe cryostat 6250 in accordance with manufacturer's instructions (refer D5429), failed to establish a maintenance protocol for the use of its Dakewe 6250 cryostat (refer to D5433), and to perform and document its hematoxylin and eosin staining characteristics (refer to D5473).
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

. Based on record review, observation, and interview with the Mohs technician, the laboratory failed to follow its quality assessment policy for one (Patient #2) of four patients reviewed. Findings include: 1. A review of the laboratory's "Quality Assurance Incident Management Plan" policy revealed a section titled "Incident Evaluation" stated, "All incidents foreseen and unforeseen are to be immediately reported to the laboratory director. Evaluations and when necessary outside consultations are to be conducted to determine the true cause (See Documentation of Problems/Discrepancies). Laboratory equipment or tissue processing errors are to be reported and recorded by the Mohs technician and reviewed with the laboratory director. Medical significance to staff or patients will be determined by the lab director, and when necessary, testing will be halted until corrective action can be taken, or incident is resolved." The section titled "Incident Documentation" stated, "All incidents will be documented by the appropriate staff (See documentation of problems/discrepancies and incident management investigation report). These will be reviewed, approved, and signed off by the lab director. If incidents are the result of staff negligence a report will be filed (See employee consultation report)." 2. An observation on 1/13/26 at 10:09 am of three of Patient #2's slides from their testing performed on 12/16/25. The frosted end of each slide had marker labeling that was covered with white-out and written over again with patient identifiers. 3. An interview on 1/13/26 at 10:09 am with the Mohs technician confirmed the slides had been labeled with the wrong patient's information. The error was discovered after the tissue was already on the incorrectly labeled slides and white out was used to correct this. 4. The surveyor requested the documentation of corrective action for the error with Patient #2 at 1/13/26 at 10:09 am and it was not made available. 5. An interview on 1/13/26 at 10:09 am with the Mohs technician confirmed this incident was not documented and resolved in accordance with the laboratory's policy listed above.

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 practice manager, the laboratory failed to include the laboratory's process for using the Histopro 414 linear stainer in the procedure manual for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Findings include: 1. The surveyor observed the laboratory on 1/13/26 at 9:16 am and saw the laboratory had one automated Histopro 414 linear stainer. 2. A review of the laboratory's "H&E Staining Procedures" explained the manual staining process and included no mention of the use of the automated Histopro 414 linear stainer. 3. An interview on 1/23/26 at 9:54 am with the practice manager confirmed the above findings.
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 practice manager, the laboratory failed to use procedures approved, signed, and dated by the laboratory director prior to use for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's patient testing log revealed patient testing started on 10/7/25. 2. A review of the laboratory's procedure manual revealed a lack of laboratory director signature and date. 3. An interview on 1/13/26 at 11:13 am with the practice manager confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . Based on record review and interview with the practice manager, the laboratory failed to establish performance specifications for its Mohs surgery histopathology testing prior to patient testing for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's patient testing log revealed its Mohs surgery histopathology testing started on 10/7/25. 2. The surveyor requested the laboratory's performance specifications on 1/13/26 at 9:56 am. 3. An interview on 1/13/26 at 9:57 am with the practice manager confirmed performance specifications were not established.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the practice manager and Mohs technician, the laboratory failed to perform weekly maintenance for its Dakewe cryostat 6250 in accordance with manufacturer's instructions for for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Findings include: 1. The surveyor observed the laboratory on 1/13/26 at 9:16 am and saw the laboratory had one Dakewe 6250 cryostat. 2. A review of the Dakewe cryostat 6250 manufacturer's instructions revealed a section titled "General Maintenance" stating, "Lubricate the specimen feeding mechanism every week: press the fast forward button to move the specimen chuck to the frontmost position, drop a drop of low-temperature lubricating oil on the copper guide sleeve, and then press the reverse button to return to the last position." 3. A review of the laboratory's cryostat maintenance and temperature log showed a lack of documentation of weekly maintenance since the laboratory started performing patient testing on 10/7/25. 4. An interview on 1/13/26 at 9:54 am with the practice manager and Mohs technician confirmed weekly maintenance was not performed.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the practice manager, the laboratory failed to establish a maintenance protocol for the use of its Dakewe 6250 cryostat for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Findings include: 1. The surveyor observed the laboratory on 1 /13/26 at 9:16 am and saw the laboratory had one Dakewe 6250 cryostat. 2. A review of the laboratory's procedure manual revealed a protocol titled "Daily Maintenance for the Leica Cryocut 1800 Cryostat", a piece of equipment not present in the laboratory. 3. An interview on 1/13/26 at 9:54 am with the practice manager confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by:

	Based on record review and interview with the practice manager and Mohs technician, the laboratory failed to perform and document its hematoxylin and eosin staining characteristics for one (1/6/26) of four patient testing dates reviewed. Findings include: 1. A review laboratory's policy titled "Control Slide Documentation" stating, "A control slide is run daily and results are documented in the control slide log (See Slide Log). This log reports the date, Mohs technician, slide number, staining technique, and stain/section results. These documents are retained on the premises for 2 years. The control slide will be the first case of the day, or a separate slide cut from deeper sections of the first tissue specimen of the day." 2. A review of four patient testing dates and the laboratory's "Laboratory Quality Control for Hematology and Eosin" log revealed there was a lack of stain characteristics documented on 1/6/26 and there were a total of three patients with histopathology testing performed that date. 3. A review of the control slides on 1/13/26 at 10:40 am for four patient testing dates showed a lack of a control slide prepared for patient testing performed on 1/6/26. 4. An interview on 1/13/26 at 10:38 am with the practice manager and Mohs technician confirmed the above findings.
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 observation, record review, and interviews, the laboratory director failed to establish performance specifications for its Mohs surgery histopathology testing prior to patient testing (refer to D6086), failed to ensure quality assessment policies were followed (refer to D6093 A), failed to ensure control procedures were followed (refer to D6093 B), failed to include the laboratory's process for using the Histopro 414 linear stainer in the procedure manual (refer to D6106 A), failed to approve, sign, and date the laboratory's test procedures prior to use (refer to D5407), and failed to establish a maintenance protocol for the use of its Dakewe 6250 cryostat (refer to D6106 C).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: . Based on record review and interview with the practice manager, the laboratory director failed to establish performance specifications for its Mohs surgery histopathology testing prior to patient testing for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Refer to D5423.
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:

A. Based on observation, record review, and interview with the Mohs technician, the laboratory director failed to ensure quality assessment policies were followed for one (Patient #2) of four patients reviewed. Refer to D5391. B. Based on record review and interview with the practice manager and Mohs technician, the laboratory director failed to ensure control procedures were followed for one (1/6/26) of four patient testing dates reviewed. Refer to D5473.

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:

A. Based on record review and interview with the practice manager, the laboratory failed to include the laboratory's process for using the Histopro 414 linear stainer in the procedure manual for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Refer to D5403. B. Based on record review and interview with the practice manager, the laboratory director failed to approve, sign, and date the laboratory's test procedures prior to use for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Refer to D5407. C. Based on observation, record review, and interview with the practice manager, the laboratory director failed to establish a maintenance protocol for the use of its Dakewe 6250 cryostat for three (October 2025 to January 2026) of three months since the laboratory started patient testing. Refer to D5433.