Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2273712	10/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Cosmetic Center Pllc	5097 Miller Road Suite 1, Flint, 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
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 record review and interviews, the laboratory failed to establish a test procedure to include microscopic examination for its histopathology testing (refer to D5403), failed to establish performance specifications for its histopathology testing before reporting patient test results (refer to D5423), and failed to perform corrective action when patient results were inaccurately reported (refer to D5779).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (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. (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 Testing Personnel #2, the laboratory failed to establish a test procedure to include microscopic examination for its histopathology testing for 5 (May 2023 to October 2023) of 5 months since the laboratory started testing. Findings include: 1. A review of the laboratory's "Dermatology & Cosmetic Center PLLC Dermatology Procedure Manual" revealed a lack of procedure to include the laboratory's process for microscopic tissue examinations for histopathology specimens. 2. An interview on 10/23/23 at 11:41 am with Testing Personnel #2 confirmed the laboratory failed to establish a test procedure to include the microscopic tissue examination for histopathology specimens.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . Based on record review and interviews with Testing Personnel #2, the laboratory failed to establish performance specifications for its histopathology testing before reporting patient test results for 5 (May 2023 to October 2023) of 5 months since the laboratory started testing. Findings include: 1. An interview on 10/23/23 at 10:00 am with Testing Personnel #2 revealed the laboratory started testing histopathology specimens on 5/9/23. 2. A review of the laboratory's "Other QA Components" policy revealed a section stating, "In addition to the responsibilities described above, when applicable, the Laboratory Director is responsible for maintaining or ensuring that designated employees maintain the following laboratory systems and components described: a. Acquisition of a CLIA Certificate that is renewed every two years b. Facility administration including protection from the warning about any physiology, chemical or biological hazards c. Test system selection d. Ordering and reordering of reagents, materials, and supplies e. Verification of Performance Specifications." 3. The surveyor requested the laboratory's establishment of performance specifications performed prior to reporting patient testing on 10/23/23 at 10:41 am and it was not made available. 4. An interview on 10/23/23 at 10:41 am with Testing Personnel #2 confirmed the laboratory had not established performance specifications prior to reporting patient test results.
D5779	CORRECTIVE ACTIONS

	CFR(s): 493.1282(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 Testing Personnel #2, the laboratory failed to perform corrective action when patient results were inaccurately reported for 1 (Patient #7) of 10 patients sent out for review. Findings include: 1. A review of the laboratory's "Patient Comparison Send Out Log" revealed 10 patient cases were sent to a reference laboratory to verify the accuracy of testing on 10/17/23. The laboratory reported Patient #7's second stage as clear on 8/14/23, and the reference laboratory reported Patient #7 as "positive for Basal Cell Carcinoma (Stage II)" on 10/19/23. 2. A review of the laboratory's "Corrective Action Policy" revealed a section stating, "Corrective action is designed to assist employees to correct job-related performance or conduct that does not meet expected or required standards at Memorial Healthcare Dermatology." and "Corrective action includes verbal coaching, formal verbal warnings and written warnings. All corrective actions will use the Request for Corrective Action Form." 3. An interview on 10/23/23 at 11:41 am with Testing Personnel #2 revealed the laboratory had not taken corrective action for the reported inaccurate test result.
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 record review and interviews, the Laboratory Director failed to ensure performance specifications were established for its histopathology testing before reporting patient test results (refer to D6082), failed to ensure corrective action when patient results were inaccurately reported was performed (refer to D6096), and failed to ensure a test procedure to include microscopic examination for its histopathology testing was established (refer to D6106).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to ensure performance specifications were established for its histopathology testing before reporting patient test results. Refer to D5423.

D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure corrective action when patient results were inaccurately reported was performed. Refer to D5779.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure a test procedure to include microscopic examination for its histopathology testing was established. Refer to D5403.