Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2298847	06/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Institute Of Detroit	24924 Michigan Avenue, First Floor, Dearborn, 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
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, the laboratory failed to include the microscopic examination and the control procedures in its Cytokeratin 5 (CK5) immunohistochemical (IHC) staining test procedure for 10 (August 2025 to June 2026) of 10 months since the test procedure was established. Findings include: 1. A review of the laboratory's "CK5 IHC Protocol" included the

	process for performing the staining and lacked both the microscopic examination and the control procedures. 2. An interview on 6/25/26 at 10:40 am with the laboratory director confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interviews, the laboratory failed to ensure its reagents and supplies had not been used when they had exceeded expiration dates for eight items observed. Findings include: 1. The surveyor observed a bottle in the laboratory labeled "Wash Buffer" with the expiration date of "12/7/25" on 6/25/26 at 9:00am. 2. The surveyor observed seven tissue marking inks in the laboratory on 6/25/26 at 9:02 am. Four of them exceeded expiration dates: a. Yellow dye expired 4/30/2025 b. Blue dye expired 6/30/2025 c. Red dye expired 8/31/2025 d. Black dye expired 6/30/2025 3. An interview on 6/25/26 at 9:02 am with testing personnel #3 confirmed the above findings. 4. The surveyor observed three total bottles of mounting medium in the laboratory with the expiration date of 2/28/26. 5. An interview on 6/25/26 at 9:14 am with testing personnel #3 and the laboratory director confirmed the above findings and confirmed the expired mounting media was currently in use.
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 laboratory director, the laboratory failed to establish performance specifications for the use of Cytokeratin 5 (CK5) immunohistochemical (IHC) staining prior to performing patient testing for one patient with testing performed. Findings include: 1. A review of the laboratory's procedure manual revealed a new "CK5 IHC Protocol" dated 8/29/25. 2. A review of patient test records revealed Patient #6, with mohs histopathology testing performed on 8/29/25, was the only patient listed to have had testing with Cytokeratin 5 (CK5) immunohistochemical staining. 3. The surveyor requested the laboratory's verification of performance specifications for the CK5 IHC stain on 6/25/26 at 10:45 am. 4. An interview on 6/25/26 at 10:45 am with the laboratory director confirmed performance specifications for the CK5 IHC stain were not available.