Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2054063	01/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Mohs Surgery Institute	303 N Hershey Rd, Bloomington, 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**
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 laboratory policy and procedure and interview with testing personnel (TP) #3 and laboratory representative, the laboratory failed to ensure that Immunohistochemical (IHC) stains procedure for Melanoma-associated antigen recognized by T cells (MART-1) contained the required components of a procedure manual since implantation in August of 2024. Findings include: 1. Interview with TP #3 at 09:55 am on 01-15-2025, stated the laboratory used the IHC stain MART-1. 2. Review of the laboratory policy and procedure manual for MART-1 IHC staining

	identified the procedure "Rapid IHC on Frozen Tissue" with the implementation date of August 2024. This procedure failed to include control procedures and the corrective action to take when control results fail to meet the laboratories criteria for acceptability for MART-1 IHC staining. 3. Interview with laboratory representative at 01:47 PM on 01-15-2025 confirmed the laboratory procedure for MART-1 IHC staining failed to include control procedures to check for both positive and negative reactivity for each time of use and the corrective actions to take when the control results fail to meet the laboratories criteria for acceptability.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure, patient testing documentation, and interview with testing personnel (TP) #3 and laboratory representative, the laboratory failed to check Melanoma-associated antigen recognized by T cells (MART-1) Immunohistochemistry (IHC) stain for positive and negative reactivity each time of use for four of four patients reviewed. Findings include: 1. Interview with TP #3 at 09:55 am on 01-15-2025, stated the laboratory used the IHC stain MART-1. 2. The Laboratory procedure "Rapid IHC on Frozen Tissue" failed to specify control procedures for MART-1 IHC staining. See D5403. 3. Review of patient testing records found for four of four patients the laboratory failed to review positive and negative reactivity each time of use of MART-1 IHC stain. A.MRN: 4243266 Date: 08-29-24 B.MRN: 3163565 Date: 09-05-24 C.MRN: 2388320 Date: 10-10-24 D.MRN: 2357633 Date: 10-24-24 4. Interview with Laboratory representative at 01:48 PM on 01-15-2025 confirmed the laboratory failed to document positive and negative reactivity for MART-1 IHC staining for the four patients reviewed.