Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2185277	10/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Derm Institute Of West Michigan, Plc The	1661 Crystal Springs Blvd Se, Caledonia, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel #2, the laboratory failed to ensure protection from chemical and biohazardous materials for one (Testing Personnel #2) of 5 testing personnel listed on Form CMS-209. Findings include: 1. The surveyor observed an open cup of coffee in the pathology laboratory on a desk between the processor and the tissue flotation bath on 10/7/24 at 9:05 am. 2. An interview on 10/7/24 at 9:08 am with Testing Personnel #2 confirmed the open cup of coffee was present in the pathology laboratory.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 interview with the Chief Finance Officer, the laboratory failed to ensure its reagents and materials were not used when they had exceeded expiration dates for two (toluene and yellow tissue marking dye) bottles observed. Findings include: 1. The surveyor observed the following reagents and materials in the Mohs dermatopathology laboratory on 10/7/24 at 9:26 am: a. OpticMount Toluene

	with the open date of 1/19/23 and the expiration date of 7/31/24. b. Mercedes Scientific Yellow Tissue Marking Dye with the expiration date of 9/30/24. 2. An interview on 10/7/24 at 9:27 am with the Chief Finance Officer confirmed the reagents and materials listed above had exceeded expiration dates. ***This is a repeated deficiency from the 12/19/22 recertification survey***
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must 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 record review and interview with the Chief Finance Officer and the Practice Manager, the laboratory failed to perform and document maintenance for the cryostat and automated stainer used in histopathology testing for 16 of 24 months reviewed. Findings include: 1. A review of the laboratory's "Daily Routine" procedure revealed a section stating, "Place Cryo-embedder, disks, and brushes in cryostat to allow for proper cooling. Place a new disposable blade in blade holder of cryostat. Change stain set up with new reagents according to stain maintenance procedure" and "Clean cryostat according to maintenance log and document in Mohs Log Folder at the end of the day." 2. A review of the laboratory's "Laboratory Maintenance" policy revealed a section stating, "The defrost cycle will be set for 11:30 pm each evening. Staining set up will be changed according to the Stain Maintenance Procedure." 3. A review of the laboratory's "Daily Temperature/Maintenance Log" revealed a lack of documentation of cryostat and stainer maintenance for the following months: a. January 2023 b. February 2023 c. April 2023 d. May 2023 e. July 2023 f. August 2023 g. September 2023 h. October 2023 i. December 2023 j. February 2024 k. April 2024 l. May 2024 m. June 2024 n. July 2024 o. August 2024 p. September 2024 4. An interview on 10/7/24 at 11:21 am with the Chief Finance Officer and the Practice Manager confirmed documentation of cryostat and autostainer maintenance for the months listed above were not present.