Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2293120	02/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dermdox Mohs Center	6 Brookhill Square S, Sugarloaf, PA	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of microscope maintenance logs, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to retain evidence of analytic system activities (microscope maintenance log) for 1 of 2 microscopes from June 2024 to December 2024. Findings include: 1. On the day of the survey, 2/11/26 at 11:00 am, the laboratory could not provide documentation of the maintenance logs for the Olympus microscope (S/N 2J21013) for the following months in 2024: - June - July - August - September - October - November - December 2. The LD confirmed the above finding on 2/11/26 at 12:00 pm.
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 of the laboratory, lack of maintenance records, and interview with the Laboratory Director (LD), the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 fumehood and 1 of 1 linear stainer used in the Histopathology laboratory from December 2025 to the day of

	survey. Findings Include: 1. On the day of the survey, 02/11/2026 at 10:00 am, observation of the laboratory revealed the following instrumentation had maintenance completed in December 2024 and due December 2025: - 1 of 1 Avantik G30 fumehood (serial number 12054912) - 1 of 1 Epredia Linistat Linear Stainer (serial number LS7849A2308EP) 2. The laboratory could not provide maintenance/function check records for the fumehood or linear stainer used in the histopathology laboratory after December 2025. 3. The LD confirmed the findings above on 02/11/2026 at 1:00 pm.
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 review of the laboratory's maintenance procedures and logs, lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to perform, and document established maintenance activities to ensure accurate and reliable test result reporting for 1 of 1 microscope used to perform dermatopathology microscopic examinations in 2025. Findings include: 1. The laboratory's daily maintenance procedure stated, "All laboratory equipment is to be cleaned daily when laboratory is in use. Manufacturer's recommendations are to be followed concerning daily maintenance of each piece of equipment. Follow procedure for microscope care, and document." 2. On the day of survey, 02/11/2026, at 11:30 am, review of the laboratory's maintenance logs revealed the laboratory failed to document the microscope care performed for 1 of 1 Olympus BX41 microscope used to perform dermatopathology microscopic examinations in October 2025. 3. The laboratory performed 1500 dermatopathology microscopic examinations in 2025. (CMS 116, estimated annual volume, dated 02/11/2026). 4. The LD confirmed the findings above on 02/11/2026 at 1:00 pm.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to follow their own established written policy for 1 of 1 procedure manual that required yearly approval by the laboratory director from 01/01/25 to date of survey. Findings include: 1. The laboratory's formal policy statement stated, "This procedure manual is reviewed by the Laboratory Director annually and at other times as required by major changes in procedure or other circumstances affecting laboratory performance of the

	test". 2. On the day of the survey, 2/11/26 at 10:15 am, the laboratory could not provide documentation of the laboratory director's review (signature) of the procedure manual for 2025. 3. The LD confirmed the above findings on 2/11/26 at 12:15pm.
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: Based on review of the laboratory's quality assurance (QA) policies, lack of documentation, and interview with the Clinical Lead LPN (CLLPN), the laboratory director (LD) failed to ensure established quality assessment (QA) programs were maintained to assure the quality of laboratory services and to identify failures in quality as they occurred for 20 of 20 months from 05/16/2024 to 02/11/2026. Findings include: 1. The laboratory's Quality Assurance procedure stated "Monthly the nurse or tech will check off the monthly Quality Assurance checklist. This checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, and Post-analytic Systems. The lab director will also review and sign off the checklist monthly." 2. On the day of the survey, 02/11/2026 at 12:05 pm, the laboratory could not provide documentation for the LD review of the monthly Quality Assurance Checklists used to evaluate the General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic systems for 20 of 20 months from 05/16/2024 to 02/11/2026. 3. The CLLPN confirmed the findings above on 02/11/2026 at 12:45 pm.