Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2294476	08/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
V Dermatology	440 Cobb Street, Cadillac, 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 the laboratory's Mohs Technician (MT), the laboratory failed to establish safety procedures to ensure protection from biochemical hazards and hazardous materials for 8 (December 2023-August 2024) of 8 months of patient testing. Findings include: 1. The surveyor observed on 08/23/2024 at 11:16 am in the laboratory an unlabeled and uncovered stain wells on the Avantik Stainer. 2. The surveyor interviewed the MT 08/23/2024 at 11:16 am regarding identification of stains and disposal process and revealed that the stains were disposed of down the laboratory sink. 3. Review of the laboratory's procedure manual revealed the laboratory did not have a procedure for the disposal of biohazardous material. 4. An interview with the MT on 08/23/2024 at 3:15 pm confirmed the laboratory did not have a procedure for disposal of biohazardous material.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory's Mohs Technician (MT), the laboratory failed to utilize techniques to ensure proper preservation of specimen

	slides for 6 (#1-6) of 6 patients reviewed for specimen preservation. Findings include: 1. Record review of patient histopathology slides for patients #1-#6 revealed: a. Patient 1: Microscopic testing was performed on 12/1/2023. The specimen slide was noted to be preserved with two coverslips. Additionally patient specimen was exposed, and air bubbles were present between specimen slide and coverslip. b. Patient 2: Microscopic testing was performed on 01/19/2024. The specimen slide was noted to have air bubbles present between specimen slide and coverslip. c. Patient 3: Microscopic testing was performed 03/01/2024. The specimen slide was noted to have air bubbles present between specimen slide and coverslip. d. Patient 4: Microscopic testing was performed on 05/24/2024. The specimen slide was noted to have air bubbles present between specimen slide and coverslip. e. Patient 5: Microscopic testing was performed on 07/19/2024. The specimen slide was noted to have air bubbles present between specimen slide and coverslip. f. Patient 6: Microscopic testing was performed on 08/16/2024. The specimen slide was noted to have air bubbles present between specimen slide and coverslip. 2. An interview with the MT on 08/23/2024 at 3:15 pm confirmed that the patient slides were not prepared in a manner to ensure proper preservation.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician (MT), the laboratory failed to establish a written policy to assess and monitor staff competency for 8 months from December 2023 to August 2024. Findings include: 1. A review of the laboratory's procedure manual revealed that the laboratory did not have a competency assessment policy. 2. An interview with the MT on 08/23/2024 at 3:15 pm confirmed patient testing began in December 2023 and the laboratory did not have a competency assessment policy established.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician (MT), the laboratory failed to establish a written policy to assess and monitor quality assessment for 8 months from December 2023 to August 2024. Findings include: 1. A review of the laboratory's procedure manual revealed that the laboratory did not have a quality assessment plan. 2. An interview with the MT on 08/23/2024 at 3:15 pm confirmed patient testing began in December 2023 and the laboratory did not have a quality assessment plan established.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician (MT), the Laboratory Director (LD) failed to approve, sign and date procedure manual before use for 8 (December 2023 - August 2024) of 8 months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed it was not signed nor dated by the LD. 2. An interview with the MT on 08/23/2024 at 3:15 pm confirmed the procedure manual was in use since patient testing began in December 2023 and that it was not signed nor dated by the LD.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician (MT), the laboratory failed to establish verification of performance testing for histopathology microscopic tissue examination for 8 months (December 2023 to August 2024). 1. Record review of the laboratory's patient log revealed a lack of documentation of verification of performance testing for microscopic tissue examination conducted on 122 of 122 patients from December 2023 through August 2024. 2. An interview with the MT on date and time confirmed verification of performance testing had not been conducted for the 122 patients tested from December 2023 through August 2024.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician (MT), the laboratory failed to establish quality control procedures to monitor the accuracy and precision of the laboratory's analytic process for 8 months from December 2023 to August 2024. Findings include: 1. A review of the laboratory's procedure manual revealed that the laboratory failed to establish quality control procedures for monitoring accuracy and precision of the laboratory's analytic process. 2. An interview with the MT on 08/23/2024 at 3:15 pm confirmed patient testing began in December 2023 and quality control procedures were not established.