Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2196639	(X3) Date Survey Completed 11/05/2025
Name of Provider or Supplier H2 Dermatology	**Street Address, City, State** 5120 Midland Road, Saginaw, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director (LD), the laboratory failed to establish policies and procedures for its Mohs Testing Procedure for 8 (March 2025 to October 2025) of 8 months since testing began on 03/14/2025. Findings include: 1. A review of the laboratory's policies and procedures revealed the lack of procedures for Mohs specimen processing. 2. On 11/05/2025 at 11:00 am, the surveyor requested the laboratory's MOHS specimen processing procedures, and it was not made available. 3. On 11/05/2025 at 11:00 am, an interview conducted with the LD confirmed the procedures were not available.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 Office Manager (OM), the laboratory failed to have procedures approved, signed and dated by the Laboratory Director (LD) prior to use for 8 (March 2025 to October 2025) of 8 months reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed that

	procedures for Mohs Micrographic Surgery testing and Potassium Hydroxide (KOH) were not approved, signed and dated by the LD. 2. On 11/05/2025 at 11:45 am, the OM confirmed the policies and procedures were not signed and dated by the LD.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 Laboratory Director (LD), the laboratory failed to establish verification of performance for histopathology microscopic tissue examinations prior to reporting patient results for 8 (March 2025 to October 2025) of 8 months reviewed. Findings include: 1. A record review of 8 patient test reports revealed that verification of performance had not been conducted prior to reporting patient test results since testing began in March 2025 for the following patients: a. Patient 1 with a testing date of 03/14/2025. b. Patient 2 with a testing date of 04/16/2025. c. Patient 3 with a testing date of 05/02/2025. d. Patient 4 with a testing date of 06/30/2025. e. Patient 5 with a testing date of 07/17/2025. f. Patient 6 with a testing date of 08/26/2025. g. Patient 7 with a testing date of 09/08/2025. h. Patient 8 with a testing date of 10/27/2025. 2. The surveyor requested documentation for verification of performance for histopathology microscopic tissue examinations; however, it was not provided. 3. On 11/05/2025 at 11:00 am, an interview with the LD confirmed that verfication of performance was not conducted prior to reporting patient test results.