Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2129545	03/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Innovative Dermatology And Mohs Surgery Llc	8800 Bernwood Pkwy Unit 6, Bonita Springs, FL	

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
D0000	An announced CLIA recertification survey was conducted at Innovative Dermatology and Mohs Surgery LLC on 3/10/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200 - 42 C.F.R. 493.1230 General Laboratory Systems D6076 - 42 C.F.R. 493.1441 Laboratory Director
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory failed to at least twice annually verify the accuracy of Parasitology and Histopathology testing performed for two (2023-2024) of two years (See D5217).
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to at least twice annually

	verify the accuracy for Parasitology and Histopathology testing performed for two of two years (2023-2024). This is a repeat deficiency from the recertification survey performed 01/26/2023. Findings included: 1. The accepted Plan of Correction signed by the Laboratory Director on 02/03/2023 from the recertification survey conducted 01 /26/2023 stated "A reminder email has been/will be sent from office manager to Lab director, testing personnel and Lab tech every 3 months to ensure the proficiency testing is done...Each analyte will be tested at least two times in the year. This will be reviewed by the Lab Director." The plan of correction had a completion date of 03/01 /2023. 2. The 2023-2024 records for the Wisconsin State Laboratory of Hygiene (WLSH) proficiency records failed to include the Parasitology analyte (Scabies) test performed by the Laboratory. 3. There was no record for 2023-2024 of verification of the Histology analyte (Hematoxylin and Eosin) test performed by the Laboratory. 4. On 03/10/2025 at 1:00 PM, the Laboratory Director confirmed the laboratory had not at least twice annually verified the accuracy for Parasitology and Histopathology testing performed for 2023 and 2024 and had not followed the Plan of Correction for the recertification survey conducted 01/26/2023.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory for two (2023-2024) of two years (See D6079).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to be responsible for the overall operation and administration of the Laboratory for two of two years (2023-2024). Findings included: 1. The laboratory failed to at least twice annually verify the accuracy for Parasitology and Histopathology testing performed for 2023-2024 (See D5217). This is a repeat deficient practice. 2. The Quality Assurance Program (QAP) procedure, last approved by the Laboratory Director on 06 /24/2015, showed the Quality Systems included 4 areas: General Laboratory, Pre-

	Analytic, Analytic, and Post-Analytic. The procedure showed "Ongoing Assessment" would occur for each of the laboratory's quality systems. The Laboratory Director was responsible for this evaluation. 3. The Job Description for the Laboratory Director showed "The Laboratory Director is responsible for the overall operation and functioning of the laboratory." 4. QAP records for 2023-2024 were requested following the Laboratory's own written procedure. No records were provided for review. 5. On 03/10/2025 at 1:00 PM, the Laboratory Director confirmed there was no documentation that the Laboratory had followed the written QAP procedure and had not identified the on-going deficient practice for failure to verify the accuracy of Parasitology and Histopathology testing performed for 2023 and 2024.