Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D1097411	05/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Specialist-North Wilmington, The	3411 Silverside Road, Wilmington, DE	

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	A Recertification Survey was conducted on May 4, 2022 at approximately 9:20 am at Delaware Valley Dermatology Group, LLC. The laboratory was surveyed according to 42 CFR part 93 CLIA requirements. Specific deficiencies are as follows:
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: document review and interview, the laboratory failed to perform Proficiency Testing (PTs) as required. The findings include: 1. During document review on May 4, 2022 at approximately 9:36 am, it was noted that the PT performed by the TP on February 14, 2021 included specimens DE M21-223, DE M21-132, and DE M21-052 comprising one PT; there was no other PT performed or documented in 2021 as required. 2.At approximately 9:38 am, it was noted that there was no PT performed or documented in 2020. 3. At approximately 9:55 am, it was noted that the Quality Assessment Procedures SOP states, "The programs and methods used for Proficiency Testing and results of this testing will be evaluated by the Laboratory Director or an appropriate, designated staff member annually", not twice per year as required. 4. At approximately 11:17 am during interview, the LD confirmed there was only one PT performed in 2021 and no PTs performed in 2020.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: lack of documentation, observation and interview that the laboratory failed to document room temperature to ensure manufacturer's storage requirements were maintained. The findings include: 1. At approximately the 9:35 am on May 4, 2020 during document review it was noted the Mohs Surgery Standard Operating Procedure (SOP) states under Reagent Storage that, "Reagents are stored according to the manufacturer's instruction and temperature logs of storage sites are maintained as appropriate", but the laboratory was unable to provide any documentation of room temperature. 2. During the tour of the laboratory at approximately 10:10 am, it was observed that the Cytoseal 60 (LOT 11800, Expiration Date 9/2023) had a storage temperature of 15-30 degrees Celsius., but there was no documentation that the room temperature was within stated limits. 3. At approximately 11:15 am, during the interview, the Laboratory Director (LD) confirmed that there were no room temperature logs and room temperatures were not recorded.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: observation and interview the laboratory failed to include the address of the laboratory location where tests were performed. The findings include: 1. At approximately 9:45 am on May 4, 2022 during document review, it was noted that 6 of 6 Report Forms had no address for the laboratory printed on them. Two random reports for each of the years 2020, 2021, and 2022 were examined. 2. At approximately 11:16 am, the LD confirmed that the Report Forms did not include an address for the laboratory location where testing was performed.