Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2024863	02/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology And Skin Surgery Center, Pa	3322 Route 22 West, Branchburg, NJ	

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
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: Based on surveyor review of the Leica Operators Manual, Temperature Log (TL) and interview with Testing Personnel (TP), the laboratory failed to monitor and document Room Temperature (RT) and Humidity where Histopathology tests were performed from 3/23/17 to the date of survey. The TP confirmed on 2/21/19 at 1:20 pm that the laboratory did not document RT and Humidity.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must 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 surveyor review of the Procedure Manual (PM), the lack of a maintenance record and interview with the Testing Personnel (TP) the laboratory did not perform and document maintenance on the microscope from 3/23/17 to the date of the survey. The TP confirmed on 2/21/19 at 1:15 pm the laboratory did not perform and document maintenance on the microscope.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Test Records (TR) and interview with the Testing Personnel (TP), the laboratory failed to maintain accurate TR to ensure positive Identification (ID) of the patient in the calendar year 2018. The finding includes: 1. A review of ten Mohs Maps revealed two out of ten did not have the correct Mohs ID number. 2. The TP confirmed on 2/21/19 at 1:45 pm that the laboratory did not maintain accurate TR.
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: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to have the address of the laboratory where tests were performed on the FR in the calendar year 2018. The finding includes: 1. A review of 20 FR revealed three out of 20 did not have the correct address of the laboratory where tests were performed. 2. The TP confirmed on 2/21/19 at 1:30 pm that the address where tests were performed was not on all FR.