Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0959033	03/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
South Nassau Dermatology	2900 Hempstead Turnpike, Levittown, NY	

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 lack of calibration records for both the room and refrigerator thermometers and an interview with the testing person, the laboratory failed to maintain the certification for the thermometers. The testing person confirmed on an interview 3/16 /2022 at approximately 11:00am.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality assurance (QA) procedure manual the laboratory director

	failed to establish the frequency QA review and perform QA review. It was determined that the laboratory director failed to implement and maintain the laboratory's QA program. Findings: 1.QA review documentation was not available for review for year 2020, 2021 through survey date. 2.Lack of calibration records for thermometers. 3.It was confirmed on an interview with testing person on 3/11/2022 about 11:30am. Refer 5413