Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0686401	12/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
South Nassau Dermatology	258 Merrick Road, Oceanside, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's packet inserts for the BD Veritor Plus System for Covid-19 and interview with the laboratory director and the medical provider/testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new kit of BD Veritor opened. FINDINGS: 1. The laboratory is using the BD Veritor Plus System kit for Covid-19. The manufacturer of the BD Veritor requires that external positive and negative controls (provided in the kits) be performed with each new kit. 2. On December 30, 2020 at approximately 11:30 AM the medical provider/testing person confirmed surveyor's findings that documentation for the required external control testing was not available at survey from September 14, 2020 when testing was initiated up to survey date. 3. Approximately 40 patient specimens were tested and reported for covid-19 testing during the above time frames.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible

	case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on lack of records, interview with the medical provider/testing person and the laboratory director, the laboratory director failed to ensure that all positive and negative covid-19 results were reported to the New York State Department of Health via the Electronic Clinical Laboratory Reporting System (ECLRS). Findings: The laboratory has tested approximately 40 Covid-19 tests from September 14, 2020 when testing was initiated through the date of this survey. The Covid-19 results have not been reported to the New York State Department of Health as required. Note: As part of their response the laboratory must provide documentation that reporting to the Department of Health is either in process or completed.