Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2176959	11/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Tareen Dermatology	2720 Fairview Ave N, Roseville, MN	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish a written procedure for reporting SARS-CoV-2 results to the required health authorities in 2021. Findings are as follows: 1. The laboratory performed SARS-CoV-2 testing using the CareStart COVID-19 Antigen Test as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 11/23/21. TP1 indicated testing began in September 2021. 2. A procedure for reporting SARS-CoV-2 test results to the required authorities was not found in laboratory documents. 3. The laboratory was unable to provide a SARS-CoV-2 result

	reporting procedure upon request. 4. In an interview at 11:50 a.m. on 11/23/21, TP1 confirmed the above finding.