

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2176959	(X3) Date Survey Completed 11/29/2021
Name of Provider or Supplier Tareen Dermatology	Street Address, City, State 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
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p> <p>. Based on record review, interview with laboratory personnel, and email communication, the laboratory failed to report SARS-CoV-2 positive and negative test results for 28 of 28 days of testing in September 2021 through November 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 only employees were tested. 2. In an interview at 11:30 a.m. on 11/23/21, TP1 indicated SARS-CoV-2 results had not been reported to the appropriate health authorities from test implementation in September 2021 through October 2021. 3. Patient testing logs were not completed for the testing. A spreadsheet with November test results was reviewed on date of survey. TP1 indicated these results had been reported to the Minnesota Department of Health (MDH). The laboratory was given 5 days to provide additional testing information from September 2021 through October 2021. 4. A test record table, provided by TP1 via email on 11/29/21, was reviewed. The document included testing dates and the number of positive and/or negative results obtained each day of testing and was dated 09/16/21 - 11/21/21. The email indicated results obtained after</p>

11/21/21 had been reported to MDH. Days of non-reporting are indicated below. 2021 Days not reported September 5 October 14 November 9 5. A total of 60 SARS-CoV-2 test results were not reported as required from 09/22/21 through 11/19/21 as indicated on the test record table. 4 positive results and 56 negative results were not reported. 6. The laboratory performed 60 SARS-CoV-2 tests between 09/22/21 and 11/19/21 as indicated on the test record table. 7. In an interview at 11:50 a.m. on 11/23/21, TP1 confirmed the above findings.