

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2197836	(X3) Date Survey Completed 02/10/2022
Name of Provider or Supplier Skinology	Street Address, City, State 872 Ohio Pike, Cincinnati, OH	
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
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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: Based on record review and an interview with the Office Manager (OM), the laboratory failed to report all SARS-CoV-2 test results as required for 97 out of 97 patients tested from 12/12/2021 through 12/18/2021. Findings Include: 1. Review of the laboratory's "Work Well Medical Policies/Procedures for Reporting COVID Testing", policy and procedure provided for inspection of the SARS-CoV-2 testing and reporting found the following instructions: "...*Identify any positive test results and fill out Human Infection Novel Coronavirus case report form *Fax the completed form, results page and demographic sheet to the county in which they reside. *Stamp "faxed" on the top sheet of the packet when faxed *File the faxed documentation" 2. The laboratory's internal SARS-CoV-2 patient result worksheets were reviewed from 12/12/2021 through 12/18/2021 and found 97 individuals tested and resulted for COVID-19 as follows: positive negative daily total 12/12/2021 2 8 10 12/13/2021 3 17 20 12/14/2021 4 9 13 12/15/2021 2 10 12 12/16/2021 0 7 7 12/17/2021 3 10 13 12/18/2021 8 14 22 === 97 3. The Inspector requested the laboratory's evidence that the above mentioned 97 COVID-19 test results were reported to the Ohio Department of Health from the OM. The OM confirmed via a telephone conversation, on 12/21/2021 at 3:02 PM, "Negative results are not reported to the local health department of the individual's residence. Only positive test results are reported via fax directly to the Clearmont County Health Department". The OM further stated that the laboratory had</p>

no record of the fax transmissions to provide. The OM was unable to provide any evidence that the above mentioned 97 out of 97 COVID test results were reported to the Ohio Department of Health.