

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1026877	(X3) Date Survey Completed 10/27/2021
Name of Provider or Supplier Concordia At Sumner	Street Address, City, State 970 Sumner Parkway, Copley, 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 Laboratory Director, the laboratory failed to report all SARS-Co-V-2 test results as required for 307 out of 307 patients tested from 09/01/2021 through 10/12/2021. Findings Include: 1. Review of the laboratory's "Concordia at Sumner Reporting", policy and procedure provided for inspection of the SARS-CoV-2 testing and reporting found the following: "Positive Lab Result (Antigen Test Results)" 2. The laboratory's SARS-CoV-2 patient result reporting documentation was reviewed from 09/01/2021 through 10/12/2021 and found 307 individuals tested and resulted as negative for COVID-19. 3. The Inspector requested the laboratory's evidence that the above mentioned 307 COVID-19 test results were reported to the Ohio Department of Health from the Laboratory Director. The Laboratory Director confirmed via an electronic mail message, on 10/19/2021 at 4:14 PM, "We only report positive tests directly to the Ohio department of health. All other testing is reported to NHSN based on number tested and number positive." The Laboratory Director was unable to provide any evidence that the above mentioned 307 negative COVID test results were reported to the Ohio Department of Health.</p>