

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D0918035	<b>(X3) Date Survey Completed</b> 07/08/2021
<b>Name of Provider or Supplier</b> Concentra Urgent Care	<b>Street Address, City, State</b> 4623 Wesley Avenue Suite C, Cincinnati, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3000</b>	<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: Based on record review and an interview with the Laboratory Supervisor (LS) found that the laboratory failed to report SARS-CoV-2 test results as required for six out of six patients tested and reviewed from February 8, 2021 through June 10, 2021. Findings Include: 1. Review of the laboratory's "CareStart COVID-19 Antigen Testing" policy and procedure, approved via signature and date on 04/14/2021 and provided for inspection review of the SARS-CoV-2 testing and reporting documentation found the following statement: "3. Report the results as required to all local and state health departments." 2. The laboratory's SARS-CoV-2 patient testing and result reporting documentation was reviewed from 02/08/2021 through 06/10/2021 and found the following six out of six tested and unreported patient COVID-19 test results: 02/08/2021 4 patient results 04/19/2021 1 patient result 06/10/2021 1 patient result 3. The LS confirmed on 06/15/2021 at 4:09 PM, that the laboratory did not report, to the health department, the six out of six patient COVID test results identified during the remote inspection.</p>
<b>D5401</b>	PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on document review and an interview with the Laboratory Supervisor (LS), the laboratory failed to follow their CareStart COVID-19 Antigen Testing policy and procedure for test result reporting for six out of six patients tested between 02/08/2021 through 06/10/2021. This deficient practice had the potential to affect all six of the identified patients tested under the subspecialty of virology. Findings include: 1. Review of the laboratory's "CareStart COVID-19 Antigen Testing" policy and procedure, approved via signature and date on 04/14/2021 and provided for inspection review of the SARS-CoV-2 testing and reporting documentation found the following statement: "3. Report the results as required to all local and state health departments." 2. The laboratory's SARS-CoV-2 patient testing and result reporting documentation was reviewed from 02/08/2021 through 06/10/2021 and found the following six out of six tested and unreported patient COVID-19 test results: 02/08/2021 4 patient results 04/19/2021 1 patient result 06/10/2021 1 patient result 3. The Inspector requested the laboratory's documentation of result reporting to the health department from the LS. The LS confirmed on 06/15/2021 at 4:09 PM, that the laboratory did not follow their policy and procedure and did not report the six out of six patient COVID test results identified during the remote inspection.