

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1018811	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Broadway Creek Senior Living	Street Address, City, State 1046 N Jefferson Street, Medina, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to follow their policy and procedure regarding COVID-19 result reporting of 33 out of 33 COVID-19 tests conducted from 06/01/2021 through 08/31/2021. Findings Include: 1. Review of the laboratory's "BinaxNow Antigen/Point of Care Testing Guidance", policy and procedure provided for inspection of the SARS-CoV-2 testing and reporting documentation found the following statements: "Report ALL BinaxNOW test results to your state's designated reporting bureaus daily. Note: this may be electronic or telephonic and must include both negative and positive results. In addition, your state may designate a time by which all results must be reported daily. It is imperative that you confirm what is required by your state and follow through to avoid fines or penalties." 2. The laboratory's SARS-CoV-2 patient result reporting documentation was reviewed from 06/01/2021 through 08/31/2021 and found 33 COVID-19 individuals tested that were not reported to the Ohio Department of Health. 3. The Inspector requested the laboratory's evidence that the above mentioned 33 COVID-19 test results were reported to the Ohio Department of Health from the Laboratory Director. The Laboratory Director confirmed via a telephone interview, on 09/14/2021 at 12:27 PM, that the laboratory did not report any COVID results to the Ohio Department of Health for 07/01/2021 through 08/31/2021, however was unable to provide any of the requested evidence of the above mentioned 33 COVID test result reporting documentation for 06/01/2021 through 08/31/2021.</p>
D1002	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.

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 33 out of 33 patients tested from 06/01/2021 through 08/31/2021. Findings Include: 1. Review of the laboratory's "BinaxNow Antigen/Point of Care Testing Guidance", policy and procedure provided for inspection of the SARS-CoV-2 testing and reporting documentation found the following statements: "Report ALL BinaxNOW test results to your state's designated reporting bureaus daily. Note: this may be electronic or telephonic and must include both negative and positive results. In addition, your state may designate a time by which all results must be reported daily. It is imperative that you confirm what is required by your state and follow through to avoid fines or penalties." 2. The laboratory's SARS-CoV-2 patient result reporting documentation was reviewed from 06/01/2021 through 08/31/2021 and found 33 COVID-19 individuals tested that were not reported to the Ohio Department of Health. 3. The Inspector requested the laboratory's evidence that the above mentioned 33 COVID-19 test results were reported to the Ohio Department of Health from the Laboratory Director. The Laboratory Director confirmed via a telephone interview, on 09/14/2021 at 12:27 PM, that the laboratory did not report any COVID results to the Ohio Department of Health for 07/01/2021 through 08/31/2021, however was unable to provide any of the requested evidence of the above mentioned 33 COVID test result reporting documentation for 06/01/2021 through 08/31/2021.