

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2211535	(X3) Date Survey Completed 06/15/2021
Name of Provider or Supplier Pacifica Senior Living Chesapeake Place	Street Address, City, State 1508 Volvo Pkwy, Chesapeake, VA	
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
D0000	An announced focused survey for compliance with SARS-CoV-2 test result reporting requirements was conducted virtually for Pacifica Senior Living Chesapeake Place (formerly Chesapeake Place) on June 14-15, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance interview conducted with the executive director on 06/08/21. Specific deficiencies cited are the following and include: 42 CFR part 493 CLIA Regulation: D1002- 42 CFR. 493.1100 Condition Reporting of SARS-CoV-2 test results.
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 interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), and lack of documentation, the facility failed to follow manufacturer's IFU to establish protocols for reporting COVID-19 rapid antigen test results to the state agency during the review timeframe of January 15, 2021 to the date of the inspection on June 14, 2021. Findings include: 1. During an entrance interview with the executive director on 06/08/21, at approximately 9:00 AM, the inspector was informed that the facility utilized Abbott BinaxNOW COVID-19 Cards for rapid SARS-CoV-2 patient testing. The inspector requested to review the test procedure, policy related to SARS-CoV-2 test reporting, and evidence of reporting results to the state agency. The facility's executive director stated on 6/14/21 at approximately 11:00 AM during a virtual survey: "Our facility is under new management. I have been unable to find the previous management's reporting COVID results for this memory care facility. We do not have a policy or protocol for reporting yet, but I do know how to register online</p>

because I did so at my former position". 2. Review of the FDA's published listing of EUA's granted for COVID-19 testing as of 06/14/21 revealed an EUA was granted for the test method outlined above on 08/26/2020 and revised on 04/20/2021. The FDA published listing revealed an IFU Authorized Laboratory instruction statement: "Authorized laboratories using the product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate". 3. The executive director and sales manager confirmed the above findings on 06/15/21 at approximately 3:30 PM.

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 interviews, review of procedures, patient log sheet records, and lack of documentation, the facility failed to document reporting of SARS-CoV-2 test results as required for nine (9) of 9 test dates reviewed from January 15, 2021 to February 18, 2021. Findings include: 1. During an entrance interview with the executive director on 06/08/21, at approximately 9:00 AM, the inspector was informed that the laboratory utilized Abbott BinaxNOW COVID-19 Ag Cards for rapid SARS-CoV-2 patient testing. The inspector requested to review the test procedure, policy related to SARS-CoV-2 test reporting, and evidence of reporting results to the state agency. 2. During a virtual inspection on 6/14/21 at approximately 11 AM, the inspector requested to review patient Binax COVID-19 Test Log documentation and reporting protocols. The executive director stated: "I have not been able to locate many records at all regarding COVID-19 testing for this facility". The sales manager stated at approximately 11:30 AM: "Our former executive director, two licenced practical nurses (LPN), activity director, and medication tech performed the BinaxNow testing. I reached out to the former LPN and requested the test logs. One of the LPN's provided a partial test log". Review of the available partial test log revealed that twenty-one (21) rapid SARS-CoV-2 patient tests were analyzed from 01/15/21 to 2/18/21. Eight (8) positive and thirteen (13) negative SARS-CoV-2 results were assayed /resulted on the following dates with no evidence of reporting as required: 1/15/21, 1/26/21, 1/29/21, 2/5/21, 2/7/21, 2/10/21, 2/14/21, 2/15/21, 2/18/21. 3. The executive director and sales manager confirmed the above findings on 06/15/21 at approximately 3:30 PM.