

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2199926	<b>(X3) Date Survey Completed</b> 03/01/2021
<b>Name of Provider or Supplier</b> Harmony On The Peninsula	<b>Street Address, City, State</b> 3450 Victory Blvd, Yorktown, VA	
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>D0000</b>	An announced focused survey for compliance with SARS-CoV-2 test result reporting requirements was conducted virtually for Harmony on The Peninsula on March 1, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance telephone interview conducted on 02/22/21. Specific deficiency cited as the following: 42 CFR part 493 CLIA Regulation: D1002-42 CFR. 493.1100 Condition Reporting of SARS-CoV-2 test results.
<b>D1002</b>	<p><b>REPORTING OF SARS-CoV-2 TEST RESULTS</b></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 interviews, review of procedures, and patient log sheet records, the laboratory failed to report SARS-CoV-2 negative test results as required on fifteen (15) days during the testing timeframe of November 12, 2020 to February 25, 2021. Findings include: 1. During an entrance interview on 02/22/21, at approximately 1:00 PM, the inspector was informed that the laboratory utilized BinaxNOW COVID-19 Ag Cards for rapid SARS-CoV-2 patient testing. The inspector requested to review the test procedures, result logs, and evidence of results reporting to state agency. 2. Review of the laboratory's Binax COVID-19 Test Log documentation and reporting protocols revealed thirty-one (31) rapid SARS-CoV-2 patient tests were analyzed on seventeen (17) test dates from 11/12/20 to 2/25/21: Twenty-eight (28) negative SARS-CoV-2 results were not reported to the state agency as required on two days in November 2020 (11/12, 11/20), three days in December 2020 (12/23, 12/24, 12/30), six days in January 2021 (1/10, 1/12, 1/13, 1/18, 1/19, 1/30) and four days in February 2021 (2/8, 2/18, 2/24, 2/25). The inspector requested to review documentation that the</p>

negative results were reported to the state agency. The Executive Director stated on 3/1/21 at approximately 1:30 PM: "We reported the positive results to the health department on the website's manual portal. We have not reported any of our negative results." 3. The Executive and Regional Directors confirmed the above findings on 03/1/21 at 2:30 PM.