

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2206263	(X3) Date Survey Completed 03/24/2021
Name of Provider or Supplier Middle Peninsula Merrimac Center	Street Address, City, State 9300 Merrimac Trail, Williamsburg, 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	<p>An announced focused survey for compliance with SARS-CoV-2 test result reporting requirements was conducted virtually for Middle Peninsula Merrimac Center on March 24, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance interview conducted on 03/12/21. Based on a review of documents and interviews, the inspector found that the laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D1002- 42 CFR. 493.1100 Condition Reporting of SARS-CoV-2 test results.</p>
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 interviews, review of procedures, and patient log sheet records, and lack of documentation, the facility failed to report SARS-CoV-2 negative test results as required on seven (7) days during the testing timeframe of January 21, 2021 to March 18, 2021. Findings include: 1. During an entrance interview on 03/12/21, at approximately 1:00 PM with the Center Director, the inspector was informed that the facility utilized BD Veritor Plus System for rapid SARS-CoV-2 patient testing. 2. The inspector requested to review the facility's BD Veritor test procedures, result logs, and evidence of COVID-19 result reporting to the state agency during the virtual survey conducted on 3/24/21. Review of the facility's Test Log documentation and reporting protocols revealed eleven (11) rapid COVID -19 tests were analyzed on 7 test dates from 01/21/21 to 03/18/21: 11 of 11 negative SARS-CoV-2 results were not reported to the state agency as required on one day in January 2021 (01/21), two days in</p>

February 2021 (02/08, 02/12), and four days in March 2021 (03/05, 03/09, 03/15, 03/18). The inspector requested to review documentation that the negative results outlined above were reported to the state agency. The Center Director stated at approximately 11:30 AM: "We have not reported results to the state". 3. The Center Director confirmed the above findings on 03/24/21 at 12:00 PM.