

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0918662	<b>(X3) Date Survey Completed</b>  04/01/2021
<b>Name of Provider or Supplier</b>  Cedarfield Clinic,The	<b>Street Address, City, State</b>  2300 Cedarfield Parkway, Richmond, 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 The Cedarfield Clinic on April 1, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance interview conducted on 03/24/21. 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, patient log sheet records, and lack of documentation, the facility failed to report SARS-CoV-2 test results as required on seventeen (17) days during a testing review timeframe of January 4, 2021 to March 31, 2021. Findings include: 1. During an entrance interview with the Nurse Manager on 03/24/21, at approximately 1:00 PM, the inspector was informed that the facility utilized Abbott BinaxNow and BD Veritor Plus System for rapid SARS-CoV-2 patient testing. 2. The inspector requested to review the facility's BinaxNow and BD Veritor test procedures, result logs, and evidence of COVID-19 result reporting to the state agency during a virtual survey conducted on 04/01/21. Review of the facility's Test Log documentation and reporting protocols revealed: Three hundred sixty-six (366) rapid SARS-CoV-2 were analyzed as follows: One hundred eighty-five (185) rapid COVID -19 tests by BinaxNow from 01/04/21 to 03/31/21; One hundred seventy (181) rapid COVID -19 tests by BD Veritor from 01/04/21 to 03/31/21. Three hundred fifty-five (355) of 355 negative SARS-CoV-2 results were not reported to the</p>

state agency as required on six days in January 2021 (01/04-01/07, 01/12, 01/15), two days in February 2021 (02/16, 02/26), and nine days in March 2021 (03/03, 03/10, 03/17, 03/20, 03/23, 03/24, 03/25, 03/27, 03/31). The inspector requested to review documentation that the negative results outlined above were reported to the state agency. The center's Clinical Leader stated at approximately 2:30 PM: "I was not aware that negative results were supposed to be reported. We have reported all of our positives to the state and I can catch up the negative entries today." 3. The Clinical Leader and Nurse Manager confirmed the above findings on 04/01/21 at 2:45 PM.