

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2199951	<b>(X3) Date Survey Completed</b>  02/14/2022
<b>Name of Provider or Supplier</b>  Covid Clinic, Inc	<b>Street Address, City, State</b>  11815 Fountain Way Suite 300, Newport News, 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 unannounced CLIA on-site survey was conducted at COVID Clinic, Inc., located at 2700 Potomac Mills Circle, Woodbridge, VA 22192, on January 25, 2022 (on-site) to February 14, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The survey included on-site tour, interviews, a telephone conference and email correspondence with the Site Supervisor, Regional Manager, Territory Director and Vice President of Compliance. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows: 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 observation, interviews, testing record reviews, and lack of documentation, the facility failed to report positive and negative COVID-19 results to the state public health department on sixty four (64) testing days from November 20, 2021 until January 31, 2022 while performing one-thousand two-hundred thirty-two (1,232) patient COVID-19 tests. Findings include: 1. During an on-site survey of the COVID Clinic (a mobile COVID-19 testing site in Woodbridge, VA) on January 25, 2022 at approximately 12:20 PM, the inspector inquired of the Site Supervisor (SS) what Clinical Laboratory Improvement Amendments (CLIA) certificate the mobile site was operating under. The SS provided a computer screenshot of the CLIA certificate with the following information: COVID CLINIC, INC 11815 FOUNTAIN WAY SUITE 300 NEWPORT NEWS, VA 23606 CLIA ID NUMBER 49D2199951 2. During an interview with the SS on January 25, 2022 at approximately 12:30 PM, the SS stated</p>

the site began testing on November 20, 2021. The site performs collection of Polymerase Chain Reaction (PCR) SARS CoV-2 (COVID-19) specimens to be sent to their facility in California and performs on-site COVID-19 testing using the Accula SARS CoV-2 molecular test kit, INDICAID COVID-19 Rapid Antigen Test kit, and Assure COVID-19 IgG/IgM Rapid Test Device antibody kit. The investigator requested to review test procedures, testing personnel training and competency records, temperature records, policy related to COVID-19 testing and documentation of reporting of results to the Virginia Department of Health. The SS provided the test procedures and patient logs from December 2021 to the date of the survey, January 25, 2022. The SS stated they would provide the rest of the above listed records via email because they recently changed mobile units and the records were no longer onsite. 3. During a phone interview on January 25, 2022 at approximately 2:36 PM with the SS, Regional Manager (RM) and Territory Director (TD), the investigator asked what the process was for reporting COVID-19 results to the VDH. The TD stated a daily list is sent to an individual in California who is in charge of ensuring results are sent to the VDH. They would have them contact the inspector to provide documentation of the reporting of COVID-19 results to the VDH. 4. In an email dated February 7, 2022, the Vice President of Compliance stated, "I can confirm that we have not been reporting COVID data for Virginia Electronically. As soon as I made the discovery last week, I asked the Regional Manager to start reporting data to VDH manually per patient tested on the VDH POC Portal." 5. Review of patient testing logs from November 20, 2021 until January 31, 2022 revealed 1,232 COVID-19 tests (molecular, antigen and antibody tests) were performed on 64 testing days from November 20, 2021 to January 31, 2022. 6. In a telephone exit interview with the facility's Territory Director on February 14, 2022 at approximately 9:50 AM, the above findings were confirmed.