Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D1093849	**(X3) Date Survey Completed** 05/27/2021
Name of Provider or Supplier Community Health Clinic	**Street Address, City, State** 1957 Second Street, Richlands, 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 CLIA recertification survey was conducted for Community Health Clinic on May 25, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The initial contact and entrance interview with laboratory conducted on April 19, 2021 with off-site record review of documentation on May 24, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D3000 - 42 C.F.R. 493-1100 Condition: Reporting of SARS-CoV-2 Test Reports.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) 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 record review and interviews, the lab failed to report SARS-CoV-2 negative test results for sixty-three (63) of 63 testing dates from 09/01/20 through 03/15/21. Findings include: 1. An interview and review of available SARS-CoV-2 patient test results and daily testing logs with the primary testing personnel on 05/25/21 at 12:30 PM revealed the site performed Healgen COVID-19 IgG/IgM Rapid Test (whole blood /serum/plasma) test method on 09/01/20 and up to 03/15/21 and the CareStart COVID-19 Antigen nasopharyngeal or nasal swab test method from 01/01/21 up to 03/15/21.

	2. 123 negative results were not reported as required during the period of review (64 testing dates). 3. The laboratory performed 142 SARS-CoV-2 tests during the period of review. 4. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings.