Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0919336	04/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Family Health Clinic, Inc	600 Randolph Street, Radford, 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 at the Family Health Clinic on 04/12/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a tour of the facility, record review and interviews, the lab failed to report 57 SARS-CoV-2 (COVID-19) positive test results for 121 of 121 testing dates from 04/04/22 up to date of survey on 04/12/23. Findings include: 1. A tour of the facility, review of daily patient testing logs and interviews with the primary testing personnel, office manager and owner of the practice on 04/12/23 at 12:30 PM revealed the facility utilized the Consult Diagnostics COVID Antigen, Consult Diagnostic COVID and Flu A&B combo kits and Qualigen QuickVue COVID test kits perform to COVID-19 patient testing. During the same interview, the inspector requested to review how the lab reports positive COVID-19 results to the local health department. The owner of the practice stated that they believed they had been reporting through the Virginia Department of Health (VDH) on-line portal and would contact them for

	verification. In an email correspondence on 04/12/23 at 1423, the office manager confirmed that VDH did not have records of the lab manually reporting positive COVID patient test results for the above-specified timeframe. 2. 57 positive results were not reported as required during the period of review (121 testing dates). 3. The laboratory performed 254 COVID-19 tests during the period of review. 4. An exit interview with the office manager via telephone on 04/12/23 at 1430 confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control records (QC), lack of documentation, daily patient testing logs and interview, the lab failed to perform at least two levels of QC materials on two days for the Abbott Cell Dyn 1700 hematology analyzer on 05/16/22 and 05/17/22 and reporting 22 and 14 patients respectively. Findings include: 1. Review of the daily QC records and patient testing logs from 06/01/21 to 11/16/22 for the Abbott Cell Dyn 1700 hematology analyzer revealed lack of documentation of QC procedures for the following dates: 05/16/22- 22 patients reported, and 05/17/22- 14 patients reported. The surveyor requested to review the QC documents for the above-specified dates. The documentation was not available for review. 2. An exit interview with the lab director and primary testing personnel on 04/12/23 at 1210 confirmed the findings.