Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0919336	03/21/2019
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 March 21, 2019 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:
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control (QC) records, manufacturer package inserts (PI), instrument QC data review, daily patient testing records and interviews with testing personnel (TP) A and laboratory director, the laboratory failed to ensure that the Beckman Coulter Access 2 instrument had the correct mean value and lot number of the BioRad Lyphochek Specialty Immunoassay QC Levels 2 and 3 for the Vitamin D analyte for fifty-one (51) days and reported seventeen (17) patients. Dates of record review include November 13, 2018 to February 19, 2019. Findings include: 1. The laboratory utilizes the Beckman Coulter Access 2 instrument to perform Vitamin D

	testing. Review of the BioRad Lyphochek Specialty Immunoassay QC (Levels 2 and 3) records for the Vitamin D analyte revealed that the QC lot numbers and mean values changed (to L2 25282 and L3 25283 exp 6/30/20) on November 13, 2018. The QC printouts from November 13, 2018 and up to February 19, 2019 from the instrument revealed that the lot number for Level 2 had had not been updated to the current lot in use (printouts had lot number 25272 exp 9/30/18). 2. An interview with TP A at approximately 12:45 PM and comparison of manufacturer PI established mean value to instrument mean value for the current lot number in use revealed that the mean values for Level 2 and Level 3 was not updated according to the PI: Level 2 (25282) - Established mean value by PI 30.8, instrument mean value was 35.82. Level 3 (25283)- Established mean value by PI 99.1, instrument mean value was 101.1. TP A stated that she/he uses the manufacturer PI established mean value for assigned QC levels for the Vitamin D assay. QC procedures performed on the following dates with the incorrect mean values and Level 2 lot number information: 11/13, 14, 16, 17, 19, 20, 21, 26, 27, 29 and 30/2018, 12/3, 4, 5, 6, 7, 11, 12, 14, 17, 18, 19, 20, 27 and 28 /2018, 01/ 2, 3, 4, 7, 8, 9, 11, 15, 16, 17, 18, 21, 22, 23, 25, 28, 29 and 30/2019, 02/1, 4, 6, 8, 11, 13, 18 and 19/2019. Total of 51 days. 3. Review of daily patient testing records revealed patients assayed with the incorrect lot number and means values for the following dates: 11/26/2018- Patient 032244 and 041048 reported, 12/11/2018- Patients 061261, 032757, 090657 and 082555 reported, 12/20/2018- patient 121864 reported, 12/28/2018- patients 120536, 102968, 091661, 122449 and 011861 reported, 01/08/2019- patient 022546 reported, 01/15/2019- patients 092151 and 081656 reported, 01/17/2019- patient 060872 reported, 02/08/2018- patient 010851 reported. Total of 17 patients. 4. An interview with the laboratory director and TP A at approximately 1:30 PM confirmed the findings.