Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2128479	03/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Chp-Cvfp Liberty University Student Health	1606 Regents Pkwy, Lynchburg, 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 CVFP Liberty University Student Health Center on March 11, 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), and interview with the testing personnel C (TP C) and lab consultant, TP failed to sign two (2) of three (3) attestation statements for performance of urine microscopy and wet preparation examination in 2018. Total 3 events performed in 2018. Findings include: 1. Review of the American Academy of Family Physicians (AAFP) 2018 PT records (3 events) revealed the attestation statements for Events A and B lacked the signature of the TP who performed the urine microscopy and wet preparation examination. 2. Review of the CLIA CMS 209 form and an interview with the TP C and lab consultant at approximately 11:40 AM revealed that TP A performed Event A and TP B performed Event B. 3. An exit interview at approximately 12:00 PM with TP C and lab consultant confirmed that TP A and B failed to sign the attestation statements for the events they performed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the tour of the laboratory, manufacturer package insert (PI) and interview with testing personnel C (TP C) and lab consultant, the laboratory failed to label three (3) of 3 hematology quality control (QC) materials in use with an open-vial expiration date according to the manufacturer's PI at the date of survey. Findings include: 1. Tour of the laboratory revealed that the laboratory utilizes the Boule Con-Diff Tri Level hematology QC materials. The current vials in use (lot numbers 2181121, 2181122 and 2181123 exp 03/22/19) did not have an open-vial date nor a revised expiration date recorded. In an interview at approximately 11:45 AM, the inspector asked the TP C when the vials of hematology QC were opened and how did they track the dates of use according to the manufacturer's PI. TP C stated that the vials were opened on Thursday, March 7, 2019 and that they forgot to label the QC vials with the date. 2. Review of the Boule Con-Diff Tri Level PI revealed the following statement: "Storage- Open vial stability 14 days after opening when returned to refrigerator after each use." 3. An exit interview with the TP C and lab consultant at approximately 12: 00 PM confirmed the findings.