Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0674919	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Old Dominion University Student Health Services	4700 Powhatan Avenue, Suite 1402, Norfolk, 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 Old Dominion University Student Health Services on February 27, 2018 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:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory's 2016 and 2107 American Academy of Family Physicians (AAFP) proficiency testing (PT) records and an interview with the laboratory director and primary testing personnel at approximately 3:30 PM on 2/27 /18, it was confirmed that the laboratory failed to enroll in a PT module for blood cell identification for two (2) of two (2) calendar years reviewed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedures, American Academy of Family Physicians (AAFP) proficiency testing (PT) records, patient test logs, and an interview, the laboratory failed to document the accuracy, at least twice a year, for Wright Stain White Blood Cell (WBC) manual count and differential identification tests in 2016 and 2017 while reporting fifty-three (53) patient results. Findings include: 1. Review of the laboratory's policy manual revealed a Wright Stain Manual Differential procedure which included the statement: "Classify 100 leukocytes. Examine red blood cell (RBC) morphology, and platelets. Tech may identify common atypical or immature blood cells such as lymphs, bands, and polychromatophilic RBC's. References to abnormalities should be made to cell line". 2. Review of the 2016 and 2017 AAFP hematology proficiency testing records, a total of six (6) events, revealed no PT documentation for manual blood cell identification for leukocytes (lymphocytes, monocytes, neutrophils), RBC, or platelet morphology. The inspector requested to review accuracy checks for the Wright Stain manual differential. No records were available for review. 3. Review of the patient test logs revealed thirty-one (31) patient manual differentials were reported in 2016 and twenty-two (22) were reported in 2017. 4. In an interview with the lab director and primary testing personnel at approximately 3:30 PM on 2/27/18, it was confirmed that the laboratory failed to perform accuracy checks for their Wright Stain Manual Differential testing in two (2) of two (2) years reviewed, while reporting fifty-three (53) patient results.