Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0674919	03/31/2026
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 Services on March 31, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Old Dominion University Student Services was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D2000 - 42 C.F.R. 493.801 Enrollment and testing of proficiency testing samples, D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems.
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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel form (CMS 209), Proficiency Testing (PT) documentation, and interview, the laboratory failed to rotate Hematology Cell Identification PT samples among all testing personnel who perform patient testing in six (6) of 6 PT events reviewed. Refer to D2007.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel form (CMS 209), Proficiency Testing (PT) documentation, lack of documentation and interview, the laboratory failed to rotate Hematology Cell Identification PT samples among all testing personnel who perform patient testing in six (6) of 6 PT events reviewed. ***REPEAT DEFICIENCY*** Findings include: 1. Review of the laboratory's CMS 209 Personnel form revealed the laboratory director (LD) identified six testing personnel (TP) performing patient moderate complexity testing. 2. Review of the laboratory ' s PT records revealed participation in the Wisconsin State Laboratory of Hygiene (WSLH) program with enrollment in hematology Cell Identification (ID). The inspector noted during the review that the WSLH PT documentation for the 2nd and 3rd events in 2024, all events in 2025, and 1st event of 2026 (a total of 6 events) a lack of original written results, lack of result sheets for the Cell ID sample pictures, and that the laboratory supervisor signed all 6 events as a TP. 3. When asked during an interview on 3/31/2026 at 2:20 pm how the lab determines who reads the Hematology Cell ID pictures for PT events (rotation) and how the results were documented, the laboratory supervisor stated that they read the pictures and write down the results for 6 events.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of manufacturer's Instructions for Use (IFU), laboratory policies, documentation and interview, the facility failed to: 1. document performance of Beckman Coulter DxH 520 Hematology analyzer yearly maintenance for the calendar year 2025 (refer to D5429), and 2. perform the Beckman Coulter DxH 520 Hematology analyzer calibration verification every six (6) months for three (3) of 5 calibration verifications reviewed (refer to D5439).
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by:

	Based on a review of manufacturer's Instructions for Use (IFU), documentation and interview, the facility failed to document performance of yearly maintenance for the Beckman Coulter DxH 520 Hematology analyzer in calendar year 2025. Findings include: 1. Review of Bechman Coulter DxH 520 IFU revealed the following maintenance instruction: "Piston lubrication should be done yearly." 2. Review of the laboratory's DxH 520 Maintenance Records for April 2024 - March 2025 revealed yearly Lubricate Pistons documented as performed on 12/2/24. The maintenance records lacked documentation of yearly Piston lubrication on calendar year 2025. 3. During an interview on 3/31/2026 at 2:20pm, the laboratory supervisor confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policies, verification documentation and interview, the laboratory failed to perform the Beckman Coulter DxH 520 Hematology analyzer calibration verification every six (6) months for three (3) of 5 calibration verifications reviewed. Findings include: 1. Review of the laboratory policy for Calibration Verification, effective 3/19/24 with Lab Director signature of approval dated 3/2/26, revealed the DxH 520 Hematology analyzer calibration verification frequency defined as each 6 months. 2. Review of the lab's Hematology Performance Verification documentation revealed DxH 520 calibration verification was performed on 3/21/24, and 3/30/26. The documentation lacked calibration verification in September 2024, March 2025, and September 2025. 3. In interview at 1pm on 3/31/26, the laboratory supervisor confirmed calibration verification was missed for the timeframes listed above.