Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0016288	03/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Vpi And Student Health Services Laboratory	Mccomas Hall, Virginia Tech, 895 Washington St, Sw, Blacksburg, 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 VPI Student Health Center, Schiffert Health Center on March 5, 2026 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:
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, procedures, lack of documentation, and interview, the laboratory failed to evaluate four chemistry, one microscopy, and nine microbiology non-graded analyte challenges resulted on six of six events reviewed for calendar years 2024 and 2025. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results (2024 Events 1-3, 2025 Events 1-3), a total of 6 events, revealed that API released non-graded analyte responses for: Total Bilirubin (T Bili) due to variance on the following 3 events: API 2024 Event 1 - T Bili challenge CH-02; API 2025 Event 2 - T Bili challenge CH-07; API 2025 Event 3 - T Bili challenges CH-12; Alkaline Phosphatase (ALKP) on the following event: API 2025 Event 2 - ALKP challenge CH-06; --a total of 4 non-graded Core Chemistry challenge samples were reported by API; Vaginal Wet Prep on the following event: API 2024 Event 2 - challenge VA-02; --a total of one non-graded microscopy challenge sample was reported by API; Urine Culture Susceptibility on the following 2 events: API 2024 Event 1 - Susceptibility UR-01

	Trimethoprim/Sulfamethoxazole (Trimeth/Sulfa) API 2024 Event 2 - Susceptibility UR-06; Ciprofloxacin (Cipro) --a total of 2 non-graded microbiology urine culture susceptibility challenge samples were reported by API; Urine Culture MIC/Zone Value on the following: API 2024 Event 1 - challenge UR-01 Cipro, Nitrofurantoin, Trimeth/Sulfa; API 2024 Event 2 - challenge UR-06 Cipro; API 2024 Event 3 - challenge UR-11 Ampicllin (Amp), Cefoxitin, Cipro, API 2025 Event 1 - challenges UR-01 Amp, Cefoxitin, Cipro, Nitrofurantoin and UR-02 Amp; API 2025 Event 2 - challenges UR-06 and UR-07 Amp, Cefoxitin, Cipro, Nitrofurantoin; --a total of 7 non-graded microbiology urine culture MIC/Zone value challenge samples were reported by API. 2. Review of the laboratory's PT review documentation revealed no evaluation/verification of accuracy recorded for the non-graded challenge sample results outlined above. The inspector requested to review an evaluation for the non-graded challenges. The documentation was not available. 3. Review of the laboratory's procedures revealed a policy (title: Proficiency Testing Policy) that stated, "Nongraded and educational challenges are to be compared to the peer group and clearly documented on the evaluation form. PT results which are not graded due to lack of consensus, submitting results too late, failure to submit, etc. are to be reviewed by the manager with appropriate follow-up and documentation of corrective action of any unacceptable result." 4. An exit interview with the laboratory supervisor on 3/5/26 at 3:30 PM confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, quality assurance (QA) records, lack of documentation, and interviews, the laboratory failed to document comparison evaluations for two hematology analyzers utilized for Complete Blood Count (CBC) testing twice annually for twenty-six (26) of 26 months reviewed (timeframe: December 21, 2023 to date of the inspection March 5, 2026). Findings include: 1. During a tour of the laboratory on 3/5/26 at 10 AM, the inspector noted two Beckman Coulter DxH 520 hematology analyzers in use for CBC testing: Serial number (SN) 020451 and SN 020459 that were labeled by the laboratory as instrument #1 and #2. 2. Review of the laboratory's procedures revealed a policy (title: Responsibilities - Technical Supervisor/General Supervisor) that outlined parallel comparisons to be performed between the two analyzers which stated, "Miscellaneous Responsibilities- #3 Run comparison studies between Coulter 1 and 2". 3. Review of the laboratory's QA documentation from January 2024 to March 5, 2026 revealed that the laboratory assayed comparison samples for DxH 520 SN 020459 and SN 020451 on 4/9/25 and 10/30/25. The inspector inquired regarding comparison studies for calendar year 2024 and if the 2025 parallel comparison studies outlined above had been evaluated for acceptability. The inspector requested to review the evaluation of the comparison studies. No documentation was available for review. The laboratory supervisor stated on 3/5/26 at 12:30 PM, "We did review the data with the goal that the parameters are within ten percent but did not document what the evaluation determined." 4. An exit interview with laboratory supervisor on 3/5/26 at 3:30 PM confirmed the findings.