Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D0666659	03/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
University Of Delaware Student Health	Laurel Hall, Newark, DE	

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 validation survey was conducted at The University of Delaware Student Health on March 24, 2026, by a federal surveyor from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiencies were found during the CLIA validation survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

	Based on review of laboratory procedures and interview with the technical supervisor (TS), the laboratory failed to establish quality control (QC) procedures in the wet mount examination policy for 2 of 2 years (March 2024 to March 2026). Findings: 1. Review of the Wet mount microscopic examination procedure revealed, the laboratory did not establish QC procedures for wet mount examinations. 2. By interview on March 24, 2026 at 1:45 pm, the TS confirmed QC procedures were not established in the wet mount policy but that the laboratory had reference photographs available for all reportable elements.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I . Based on the laboratory's observations, the lack of temperature monitoring records, and an interview with the technical supervisor (TS), the laboratory failed to monitor the temperature of the phlebotomy draw room where BD (Beckon Dickinson) vacutainer tubes were stored for 2 of 2 years (March 2024 to March 2026). Findings: 1. Tour of the university hospital revealed a phlebotomy draw room next to the laboratory, where the following BD Vacutainer tubes were kept with the manufacturer stated temperature requirement of 4-25 degrees Celsius: a. 02 Blue Top Sodium Citrate tubes - Lot #5260118. b. 14 Yellow top SST (Serum Separator Tube) tubes - Lot #5324059 c. 18 Purple top EDTA (Ethylenediaminetetraacetic acid) - Lot#5260173 2. The laboratory was unable to provide temperature monitoring records for the phlebotomy draw room where the above BD vacutainer tubes were stored for 2 years (March 2024 - March 2026). 3. By interview, the TS confirmed on March 24, 2026, at 11:30 pm confirmed that temperatures were not monitored or documented in the phlebotomy draw room. II. Based on the laboratory's observations, review of manufacturer manuals, lack of temperature-monitoring records, and an interview with the technical supervisor (TS), the laboratory failed to monitor temperature and humidity controlled rooms where 7 of 7 microscopes in use. Findings: 1. Tour of the university hospital, 2nd floor, revealed the following microscopes in use for wet mount microscopic examinations: a. Olympus BH2 - Serial #228144. b. Omega Compound - Serial # 0708732 c. Omega Compound - Serial # 002853 d. Labomed Lx300- Serial #9136001 e. Nikon E200 - Serial # 844132 - Backup scope. f. Omega Compound - no serial number. g. Omega Compound - no serial number. 2. Review of a sampling on manufacters manuals revealed: a. Labomed User manual, Specification, 9. "Ambient temperature: 5 to 40C Celsius (C) (41 to 104 F) Maximum relative humidity: 80% for temperature up to 31C (88Fahrenheit (F)). b. Nikon E200 Instructions, Chapter 10 Technical Specifications, 8. Operating environment, Ambient temperature: 5 to 40C (41 to 104 F), maximum relative humidity: 80% for temperatures up to 31C (88F). 3. The laboratory was unable to provide temperature

	monitoring records for the 7 microscopes that were in use. 4. By interview, the TS confirmed on March 24, 2026, at 1:00 pm, confirmed that temperatures were not monitored or documented by the microscopes.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observations, the lack of thermometer maintenance procedures, and an interview with the technical supervisor (TS), the laboratory failed to establish maintenance protocols for 3 of 3 thermometers in use to monitor temperature and humidity in the laboratory. Findings: 1. Tour of the university hospital revealed the following 3 thermometers were used to monitor temperature and humidity in the laboratory: a. Room 103 - Min Max Thermometer Serial #17626, Calibration due 02 /2021. Used to monitor refrigerator and freezer temperatures. b. Room 101 C - Traceable NIST, no serial #, calibration due: 06/15/2000. Used to monitor temperature in the closet. c. Room 104 - Fisherbrand Min/Max thermometer, serial #2021D1205184. Used to monitor room temperature and humidly in the laboratory. 2. The laboratory was unable to provide a procedure for thermometer maintenace/ calibration. 3. The TS confirmed on March 24, 2026, at 11:30 pm that the laboratory did not establish procedure for thermometer maintenance/ calibration.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of quality control (QC) records and interview with the technical supervisor (TS) the laboratory failed to perform negative and positive control materials each day patient testing for the CorDX Tyfast Multiplex Rapid test for 2 of 2 years (Macrh 2024 to March 2026). Findings: 1. Review of the food and drug administration (FDA) medical device data base, revealed the CorDX Tyfast Multiplex Rapid test used to analyze SAR-CoV-2, and Influenza A/ B was not designated a test complexity. 2. Review of the laboratory procedure and QC revealed QC records was not performed each day of patient testing. 3. From March 2024 to March 2026, the laboratory performed 1,839 CorDX Tyfast Multiplex Rapid test. 4. By interview the TS confirmed on March 24, 2026 at 2:30 pm, QC was not performed each day of patient testing, but rather for each new lot and shipment of CorDX Tyfast Multiplex Rapid tests.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control

	materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the technical supervisor, the laboratory failed to document Camco Quik Stain II staining materials for its intended reactivity for 2 of 2 year (March 2024 to march 2026). Findings: 1. The laboratory was unable to provide documentation for Camco Quik Stain II staining materials for their intended reactivity for 2 of 2 year (March 2024 to march 2026). 2. By interview the TS on March 24, 2026 confirmed the laboratory QC records for the Camco Quik Stain II did not include documentation of the staining materials intended reactivity.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, testing personnel (TP) competency assessment records, and an interview with the technical supervisor (TS), the laboratory failed to evaluate and document the performance of high-complexity testing at least semiannually during the first year for l of 1 TP hired in 2025. Findings: 1. The personnel qualification, competency, and continuing education procedures under training and competency stated, "...Competency was assessed upon hire, at 6 months, and annually thereafter..." 2. The laboratory could not provide 6-month and annual competency assessments for TP #10, who was hired April 2025. 3. By Interview on March 24, 2026, at 11:35 a.m., the TS confirmed that TP #10 was not assessed for 6-month competency in 2025.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: A review of testing personnel competency assessment records and an interview with technical supervisor (TS), the TS failed to document annual competency for 2 of 10 Testing Personnel. Findings: 1. Review of competency assessment records included cover sheets listing the six assessment elements, but did not include documented proof of activities/ assessments performed for each element in 2024 and 2025 for 2 testing personnel. (TP#9 and TP#10). 2. TP # 9 and #10 only analyze microscopic wet mount examinations. 3. Interview with the TS on March 24, 2026, confirmed the TS did not document the assessment of the required six-elements of competency for the above 2 testing personnel.