Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D0662985	06/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Delaware Public Health Laboratory	30 Sunnyside Road, Smyrna, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based upon direct observation, review of policies and procedures, review of test records, and interview of facility personnel, the laboratory failed to have written procedures for the collection, storage and handling and transportation of specimens submitted by outside providers in the testing for 5 of 5 subspecialties. The findings included: 1. Upon observation of the processing section of the laboratory on June 4, 2025 at 9:30 AM the laboratory received specimens from outside sources via courier. The specimens were transported from the vehicle to the laboratory in a compartmentalized cooler, where temperatures were taken to ensure samples were within 2 to 8 degrees C. 2. Review of the laboratory's own written policy revealed no written procedures or policies for the collection, storage, handling and transportation of specimens submitted by outside providers. 3. A review of test records indicated a laboratory total annual test volume of 58,300 for the following five active CLIA subspecialties and associated codes: 110 Bacteriology, 115 Mycobacteriology, 140 Virology, 210 Syphilis Serology, 220 General Immunology. 4. In an interview on June 4, 2025 at 9:40 AM, the supervisor of the processing section, as well as the quality assurance manager confirmed that the laboratory was in the process of creating a policy and procedure guide for the pre-analytic portion of processing samples, including specimen transport temperature requirements and rejection criteria, but did not have one completed and approved at the time.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions, review of patient records, and confirmed in interview with the Technical Supervisor (TS), the laboratory failed to follow manufacturer's instructions in ensuring Trichomonas Vaginalis specimens were not run on patients under the age of 14 for 15 of 8,246 Trichomonas Vaginalis specimens run on the Hologic Panther analyzer for 6 months reviewed. Findings Included: 1. A review of manufacturers instruction for the Aptima Combo 2 Assay Panther System (502446 Rev. 009) stated the following on page 20: "Limitations: P. The performance of the Aptima Combo 2 Assay has not been evaluated in adolescents less than 14 years of age." 2. A review of the laboratory's Laboratory Information Management System (LIMS) patient report generated from October 2024 to December 2024 and March 2025 to May 2025 (random review) showed 15 patient specimens whose age demographics fell under the age of 14 at the time of testing. 3. In an interview on 6/3/2025 at 1:57 PM, the TS of Microbiology confirmed that 15 of 8,246 Trichomonas Vaginalis patient specimens tested between the date ranges October 1 to December 31, 2024 and March 1 to May 31, 2025, according to the LIMS report, were of patients under the age of 14. II. Based on direct observation, review of the Becton Dickinson BBL Lowenstein-Jensen (L-J) Medium manufacturer's instructions, and confirmed in interview with the Technical Supervisor (TS) of Microbiology, the laboratory failed to ensure manufacturer's instructions were followed for storage/stability for 35 of 35 L-J media slants. Findings included: 1. Review of Becton Dickinson BBL Lowenstein-Jensen (L-J) Medium package insert (L007464, Rev. 11, October 2015) states, "Storage Instructions: On receipt, store tubes and bottles in the dark at 2-8 degrees C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Media stored as labeled until just prior to use may be inoculated up to the expiration date ..." 2. During a tour of the Microbiology department on 4/18/2024 at 1:32pm, 35 tubes of Becton Dickinson BBL L-J media, slant tubes, Lot 4185447, expiration date 2026-01-03, were observed in storage exposed to light in refrigerator DPHL MB00035 ISEN600016. 3. During an interview on 6/3/2025 at 2:59 pm, the TS of Microbiology confirmed the findings of the L-J media slant tubes being exposed directly to light.
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: Based on direct observation, manufacturer's instructions, review of Insensix temperature ranges, and interview with the laboratory's quality assurance manager, the laboratory failed to define temperature ranges consistent with the manufacturer's instructions, where temperature dependent reagents and supplies were located at room temperature within the microbiology section and within 1 of 2 freezers. Findings Included: 1. In direct observation, on 6/3/2025 in the Microbiology section, the following reagents and supplies were found within the corresponding areas: a. Freezer DPHL MB0016 ISEN600024 (-31 to -15 degrees Celsius) - i. 3 Becton Dickinson BBL Meropenem Sensi-Disc boxes, Lot # 4120704, Manufacturer Storage Requirement -20 to -8 degrees Celsius ii. 1 Liofil Chem MIC Test Strip (Ceftazidime /Ceftazidime+Clavulanic acid), Lot #121923050, Manufacturer Storage Requirements -20 degrees Celsius iii. 1 Biomerieux ETEST Vancomycin Box, Lot #1011087740, Manufacturer Storage Requirements -20 to -8 degrees Celsius iv. 4 Bruker US IVD BTS Calibration Standards for MBT-CA System, Lot #6030424002, Manufacturer Storage Requirements -18 degrees Celsius b. Microbiology Gram Staining Bench ISEN600092 (15 to 30 degrees Celsius) - i. 1 Remel Gram Safranin bottle, Lot #138499, Manufacturer Storage Requirements 20 to 25 degrees Celsius ii. 1 Remel Gram Decolorizer bottle, Lot #137758, Manufacturer Storage Requirements 20 to 25 degrees Celsius iii. 1 Remel Gram Iodine bottle, Lot #140674, Manufacturer Storage Requirements 20 to 25 degrees Celsius iv. 2 Becton Dickinson Phoenix NMIC-306 boxes, Lot #5070931, Manufacturer Storage Requirements 15 to 25 Celsius v. 1 Becton Dickinson Phoenix PMIC-110 boxes, Lot #5063745, Manufacturer Storage Requirements 15 to 25 Celsius vi. 2 Becton Dickinson Pheonix NID boxes, Lot# 5085911, Manufacturer Storage Requirements 15 to 25 Celsius 2. In an interview on 6 /3/2025 at 3:12 PM, the TS of Microbiology and the laboratory's quality assurance manager confirmed that temperatures ranges set for the aforementioned freezers and room temperature overall were not consistent with manufacturer storage requirements of reagents and supplies stored.
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 review of manufacturer's instructions, laboratory maintenance records (3/1 /25-6/3/25), test volume records, and interview with the Technical Supervisor (TS) of Microbiology, as per the Form CMS-209, the laboratory failed to follow the operator's manual for the Hologic Panther System for daily maintenance requirements and cleaning for 3 of 3 months. Findings included: 1. A review of manufacturer's instructions (AW-20220-001 Rev. 001) for the Hologic Panther revealed the following maintenance requirements for the mag wash cleaning: "As part of system maintenance, it is required that this task be performed after each testing day. For example, if processing test orders on Monday-Friday, schedule the Mag Wash Clean task to be run after working hours on Monday-Friday." 2. A review of the laboratory's maintenance record titled, "Delaware Public Health Lab Panther Fusion Maintenance Log Report" from March 1, 2025 through June 3, 2025 revealed the laboratory failed to follow manufacturer's instructions to perform daily Mag Wash Clean maintenance after each day testing was performed on the following Hologic Panther Fusion

	Analyzers: Serial Numbers # 01190, 01282 3. A review of the laboratory's test volume records between March 1, 2025 through June 3, 2025 showed daily Mag Wash Clean maintenance was not performed after testing for the following: Serial Number 00190 - 1760 CT/GC specimens, 124 qHCV specimens, 689 Trichomonas Vaginalis specimens Serial Number 01282 - 2,914 CT/GC specimens, 142 qHCV specimens, 2,277 Trichomonas Vaginalis specimens 4. In an interview on 6/03/25 at 3:18 PM, the TS of Microbiology confirmed the Mag Wash settings were not set to run after each testing day. Word Key: GC- Neisseria gonorrhea CT-Chlamydia trachomatis qHCV-Quantitative Hepatitis Virus
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of laboratory policies, test records, and confirmed in interview the laboratory director failed to ensure the laboratory provided quality services for preanalytical phases of testing for 5 of 5 subspecialties. Findings Included: 1. Review of the laboratory's own written policy revealed no written procedures or policies approved, or signed by the laboratory director for the collection, storage, handling and transportation of specimens submitted by outside providers. 2. A review of test records indicated a laboratory total annual test volume of 47,854 for the following five active CLIA subspecialties and associated codes: 110 Bacteriology, 115 Mycobacteriology, 140 Virology, 210 Syphilis Serology, 220 General Immunology. 3. In an interview on June 4, 2025 at 9:40 AM, the supervisor of the processing section, as well as the quality assurance manager confirmed that the laboratory was in the process of creating a policy and procedure guide for the pre-analytic portion of processing samples, including specimen transport temperature requirements and rejection criteria, but did not have one completed and approved by the laboratory director at the time.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on laboratory personnel interview and laboratory policies and procedures record review, the laboratory director, high complexity testing, failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each

	individual is authorized to perform, whether supervision is required for specimen processing, test performance, or result reporting and whether supervisory or director review is required prior to reporting patient test results. Findings included: 1. The laboratory quality assurance manager confirmed on June 4, 2025 at 09:20 am that the laboratory maintained no documentation to indicate that the laboratory director had specified, in writing, the responsibilities and duties of each laboratory staff as required by this regulation. 2. According to laboratory documents, the laboratory performed and reported approximately 58,300 patient test results annually.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on review of the laboratory's post-relocation instrument performance verification records, test records and interview, the Technical Supervisors of Microbiology and Virology failed to approve the verification of the test procedures performed and establishment of the laboratory's test performance prior to running patient samples for 4 of 4 test systems/instrumentation. Findings Included: 1. A review of the laboratory's post-relocation/move instrument performance verification records revealed the following information: a. Abbott Architect i1000, relocation /move date March 2025, verification performed April 4, 2025, technical supervisor sign-off date May 13, 2025. b. 2 Hologic Panthers (S/Ns #01190, 01282), relocation /move date April 2025, verification performed April 10, 2025, technical supervisor sign-off date April 29, 2025. c. 9 Fisher Scientific ABI 7500 Fast Dx, relocation/move dates S/N 275000961 (4/15/25), S/N 275011244 (4/15/25), S/N 275011803 (4/18/25), S/N 275030208 (4/18/25), S/N 275030208 (4/18/25), S/N 275030689 (4/23/25), S/N 275031535 (4/23/25), S/N 275031536 (5/2/25), S/N 275031953 (4/29/25), S/N 275031955 (4/29/2024), no technical supervisor sign-off until 5/20. d. 3 Illumina MiSeq Systems, relocation/move date October 2024, no instrument verification performed until February 2025, no technical supervisor sign-off until 2/25. 2. A review of the laboratory's test records revealed the following tests run between the time instruments were moved, before the technical supervisor reviewed and signed off on the post-relocation/move instrument performance verification: a. Abbott Architect i1000, date range 4/03/25 to 5/13/25: i. HCV-152 tests ii. HepB AUSAB-156 tests iii. HepB_Conf-2 tests iv. HepB-Core-156 tests v. HepB-CoreM-8 tests vi. HepB Surface Ag-156 tests vii. HIV EIA-65 tests viii. Syphilis TP-412 tests b. Hologic Panther, date range 4/10/25 to 4/29/25: i. CT/GC-1203 tests ii. Trichomonis Vaginalis-798 tests iii. qHCV-0 c. Fischer Scientific ABI 7500 Fast Dx, date range 4/15/25 to 5/20: i. Pertussis-18 tests ii. Flu/SC2-2805 tests iii. Measles-24 tests iv. Mumps-24 tests v. Non-variola-16 tests vi. Orthopox-16 tests vii. HSV/VZV-340 tests viii. TB-136 tests ix. Trioplex-14 tests x. Y.pestis-5 tests xi. F. tularensis-4 tests xii. Burkholderia-4 tests xiii. Brucella-6 tests xiv. B. anthracis-4 tests d. Illumina MiSeq Systems, date range 10 /24 to 2/25 i. M. tuberculosis-7 tests 4. In an interview on 6/4/25 at 9:20 AM, the laboratory's quality manager confirmed the technical supervisors did not sign-off and ensure completion of instrument verification post relocation, prior to running patient samples.