Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D0662985	06/10/2021
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
D0000	Federal Jurisdictional Survey Federal surveyors from the Division of Clinical Laboratory Improvement & Quality CLIA Operations, Centers for Medicare and Medicaid Services (CMS) - Philadelphia CMS Office conducted an announced CLIA Recertification survey at the Delaware Public Health Laboratory. The laboratory is on compliance with 42 CFR part 493 with standard level deficiencies cited:
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of patient testing record and interview with staff, the laboratory failed to ensure that the Lab LIMS Sample Window solicited the correct collection times of specimens for 4 of 4 patients reviewed, as evidenced by: In review of the 4 patient testing records, the collection time is different or missing in the requisition form comparing to the Lab LIMS Sample Window. a. Sample # 1510686 default collection time @ 6/3/21 in LIMS 02:07:41 PM; in lab requisition form 2119 b.

	Sample # 1506380 default collection time @ 5/24/21 in LIMS 01:44:36 PM; in lab requisition form 08:47 c. Sample # 1511712 default collection time @ 6/8/21in LIMS 02:16:48 PM; in lab requisition form: Blank d. Sample # 1511708 default collection time @ 6/7/21in LIMS 02:15:15 PM; in lab requisition form: Blank During an interview on 6/9/2021 at approximately 1 PM, the laboratory's Technical Supervisor #2 (TS2) confirmed above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of documentation and interview, the laboratory failed to have a procedure available for the test "TaqPath COVID-19 Combo Kit EUA Method." Findings: 1. During a review of the laboratory's documentation on 6/9/2021, the surveyor could not locate a procedure for "TaqPath COVID-19 Combo Kit EUA Method." 2. During an interview on 6/10/2021 around 10:30 am TS#2 confirmed that a procedure was unavailable for this test method and that this test method.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations and interview, the laboratory failed to label reagents and material with proper expiration dates. During a laboratory tour on 6/8/2021 at 10:30 am reagent labels read: 1- W8-1 Water Thermo Scientific Lot 185459 opened date 2 /25/2019. 2- Formic Acid EMSURE 98-100% CAS No: 64-18-6 Received date 10/12. 3- 3% H2O2 (Hydrogen peroxide) lot 127863 dated 12/17/18 (Handwritten label). 4- No expiration dates indicated for 1, 2 and 3. During an interview on 6/8/2021 at approximately 12 PM, the laboratory's Technical Supervisor #3 (TS3) confirmed above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to verify performance specifications prior to patient testing for SARS-CoV-2 PCR testing and SARS-CoV-2 IgM testing. Findings: 1. During a tour of the laboratory on 6/9/2021 it was noted the laboratory has Applied Biosystems 7500 Fast Dx Real-time PCR Instruments (ABI) with the following serial numbers: a. 275000961 b. 275011244 c. 275011803 d. 275030208 e. 275030689 f. 275031535 g. 275031536 h. 275031953 i. 275031955 2. During a record review of "Flu-SC2 Multiplex Verification" on 6/9/2021, it was noted that accuracy was not verified for the following serial numbers: a. 275000961 b. 275011803 c. 275031953 d. 275031955 3. During a record review of "SARS-CoV-2 Thermo Kingfisher verification" on 6/9/2021, it was noted that accuracy was not verified for the following serial numbers: a. 275000961 b. 275031953 c. 275031955 4. TS#2 confirmed the findings during an interview on 6/10/2021 around 10:00 am. 5. During a record review of "Abbott Architect SARS-CoV-2 IgM verification" on 6/9 /2021 around 1pm, it was noted that precision had not been verified prior to patient testing. 6. TS#4 confirmed the findings during an interview on 6/9/2021 around 1:00 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 observation and interview the laboratory failed to maintain calibration up to date to ensure proper calibration for below instruments: 1. A tour of the laboratory on 6/8/2021 at 10:30 AM, where the surveyors found below instruments (Pipettes) out of date for calibration and maintenance: a. Eppendorf 10 Micro litter Pipette; Pipette Serial No I62307H; No sticker b. Eppendorf Pipette; Pipette ID: 2036768; Calibrated: 10/15/19; Next due: Blank c. Eppendorf Pipette; Pipette ID: 4129135; Calibrated: 10 /15/19; Next due: Blank d. Eppendorf Pipette; Pipette ID: 3344267; Calibrated: 10/4 /19; Next due: Blank e. Pipette ID: 161611A; Calibrated: 10/9/19; Next due: 4/9/20 f. Pipette ID: 3524038; Calibrated: 10/16/19; Next due: 4/16/20 g. Pipette ID: 474313; calibrated: 10/16/19; Next due: 4/16/20 h. Pipette Serial No 11000170/V1222; No sticker i. Pipette Serial No 11001450/V1221; No sticker 2. During an interview on 6/8 /2021 at approximately 2 PM, the laboratory's Technical Supervisor #3 confirmed above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

	they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview, the laboratory failed to monitor 2 of 2 IQCP plans over time. Findings: 1. During a review of the laboratory's documentation on 6/8/2021 the documents "MQ002 IQCP AST," and "MQ003 IQCP MediaQC," were last updated on 8/26/2019 to reflect the past 12 months of data. 2. During an interview on 6/8/2021 around 12:40pm TS#3 confirmed that the IQCPs had not been monitored over time.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and interview two technical supervisors failed to evaluate the competency of 5 of 37 personnel during 2019 and 2020. Findings: 1. The laboratory's standard operating procedure (SOP) "Quality Assurance Plan" states under Competency Assessment, "Laboratory Section Managers or other designated technical managers must assess competency for all analyses performed at the DPH Laboratory." 2. Based on lack of documentation the following competency assessments were unavailable at the time of the survey: For the Microbiology section: a. TS#3 was missing TB, Bioterrorism, and Routine Bench competency for 2019 and 2020 b. TP#4 was missing TB and Routine Bench competency for 2020 c. TP#5 was missing Bioterrorism and Routine Bench competency for 2020 d. TP#8 was missing Routine Bench competency for 2020 For the Sexually Transmitted Infections section: a. TS#4 was missing Abbott Architect, Syphilis, and Hologic Panther competencies for 2019 and 2020 3. During an interview with TS#3 on 6/8/2021 around 11 am, she confirmed the findings for the Microbiology section. 4. During an interview with TS#4 on 6/9/2021 around 1 pm, she confirmed the findings for the Sexually Transmitted Infection section.