Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0881184	11/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Public Health And Environmental	3 Schwarzkopf Drive, Ewing, NJ	

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	The Centers for Medicare & Medicaid Services (CMS) CLIA Branch Location federal surveyors conducted an announced CLIA recertification survey of the New Jersey Public Health and Environmental Laboratory on October 31, 2023 to November 2, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiencies were found during the announced routine CLIA recertification survey performed October 31, 2023 to November 2, 2023.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of the laboratory temperature and humidity records and interview with the Quality Assurance Coordinator and technical supervisor (TS) #5, the laboratory failed to define low humidity criteria for the virology laboratory from 2022 to the day of survey. Findings Include: 1. The PHEL Temperature and Humidity Logs for laboratories L315, L320A and L320B state humidity range Less than or equal to 75%. 2. A sampling of instrument manufacturer documents Environmental Conditions - Relative Humidity's stated: - EPlex = 15 - 85%. - Panther Hologic = 20 - 85%. - Vidas = 15 - 85%. - GeneXpert = 15 - 85%. 3. Review of The PHEL Temperature and Humidity Logs for laboratories L315, L320A and L320B from 2022 to 2023 on November 2, 2023, revealed there were no established low limits for Humidity. 4. The following months in 2022 and 2023 the PHEL Temperature and Humidity Logs for

	laboratories L315, L320A and L320B stated humidity "low" and not an actual measured humidity %: 2022: - L315: January, February, March April, May, October, November and December. - L320A: January, May and November. - L320B: January, October and November. 2023: - L315: January, February, March April, May and June. - L320A: January, February and May. - L320B: February, April and May. 5. The Quality Assurance Coordinator and TS#5 confirmed a low Humidity limit had not been established for the laboratories from January 2022 to November 2023.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the oxidase reagent quality control (QC) records and interview with the Quality Assurance Coordinator, the laboratory failed to not use an expired lot of oxidase reagent made in house from April 2023 to May 2023. Findings Include: 1. The oxidase reagent was made in house on April 5, 2022 and expired on April 5, 2023. 2. Review of the oxidase reagent QC records on October 31, 2023 revealed, the oxidase reagent (Lot# 076K18141) was used past its expiration date (April 5, 2023), as the April and May of 2023 oxidase reagent QC logs stated the reagent expiration date as May 5, 2023. 3. The laboratory was unable to provide documentation as to why the reagents expiration date was extended to May 5, 2023. 4. The oxidase reagent was used for two patients in April 2023 and five patients in May of 2023. 5. The Quality Assurance Coordinator confirmed no documentation was available to support the extension of the expiration date of the oxidase reagent on November 2, 2023 at 11: 45 am.
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 record review, observations, and interviews with TP#18, the laboratory failed to perform maintenance at the frequency specified by the manufacturer. Findings include: 1. The instructions for use for the SPH1240 states: "To keep the SPH1240 in optimal condition, preventative maintenance is required at regular intervals but at least one time per year." 2. During a tour of the laboratory on November 2, 2023 at 11:10 am, it was noted that the SPH1240 maintenance sticker had a preventative maintenance performance date of 30 Aug 2022 and an expiration date of 29 Aug 2023. 3. During an interview on November 2, 2023 at 11:10 am, TP#18 confirmed that the preventative maintenance was overdue for the SPH1240. 4. During a tour of the laboratory on November 2, 2023 at about 11:30 am, it was noted that the 7500-2 preventative maintenance was due on 10/1/2023. 5. During an interview on November 2, 2023 at about 11:30 am, TP#18 confirmed that the 7500-2 preventative maintenance was overdue.