Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0881184	12/02/2021
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	An announced CLIA recertification survey was performed at the New Jersey Public Health and Environmental Laboratories on November 30, 2021 to December 2, 2021 by the CMS New York CLIA Branch Location federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The specific deficiencies are as follows:
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of standard operating procedures (SOP) and an interview with the testing person, the Field Deployable Laboratory (FDL) failed to provide an approved procedure manual for the Cepheid GeneXpert Xpress SARS- CoV-2/Flu/RSV Assay . Findings include: 1. On December 1, 2021 at approximately 2:30 PM ,during a review of procedure manual documentation the surveyor requested the SOP for the Cepheid GeneXpert Xpress SARS-CoV2/Flu/RSV assay. 2. The FDL Testing Person (TP1) stated "An element still has to be added for the procedure to be finalized". 3. During the exit interview with the laboratory director on December 2, 2021 at 5:00 pm confirmed the above findings.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test

	system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing person, the Field Deployable Laboratory (FDL) section of the virology program failed to perform verification of the lot number for control materials for GeneXpert cartridges prior to the use for testing. Findings include: 1. On December 2, 2021 during a tour of the storage facility for the Field Deployable Laboratory (FDL) section of the virology program, the surveyor observed multiple GeneXpert Cartridge kits used for the Cepheid GeneXpert Xpress SARS- CoV-2/Flu/RSV Assay and inquired how does the laboratory verify the acceptability of the control materials? 2. The FDL Testing Person (TP1) stated " we don't perform kit lot to lot studies ". The absence of control verification documents verified the TP statement. 3. During the exit interview with the laboratory director on December 2, 2021 at 5:00 pm confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review of PHEL Temperature & Humidity Log and interview with the general supervisor of the molecular virology section the laboratory failed to perform corrective action for temperature readings out of range for two consecutive months for August 2021 and September 2021. Findings include: On November 30,2021 during a review of the molecular virology " PHEL Temperature and Humidity Log" for laboratory room: L325 revealed the following: 1.The Digital Thermometer Reading a.22 of 22 days for the month of August 2021 the temperature reading was not in the of 20C to 30C Temperature Range. b.19 of 21 days for the month of September 2021 the temperature reading was in the 20C to 30C Temperature Range i. 2 of 21 days the temperature tracking logs was blank, comments and tech initials were absent. 2.Humidity Reading a.13 of 22 days for the month of August 2021 the humidity was greater than acceptable range for the Humidity limits of less than or equal to 60%. b.10 of 19 days for the month of September 2021 the humidity was greater than acceptable range for the Humidity limits of less than or equal to 60%. i. 2 of 21 days the humidity tracking logs was blank, comments and tech initials were absent. 3. At approximately 2:20 PM , during an interview with the molecular virology general supervisor (GS), the surveyor requested corrective action documentation. The (GS) stated " I didn't fill out a non-conforming event (NCE) form due to the temperature problem being a building wide issue" 4. During the exit interview with the laboratory director on December 2, 2021 at 5:00 pm confirmed the above findings.