Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0881184	06/28/2019
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by the Quality Assurance officer, the laboratory failed to follow its written policies and procedures to assess the competency of eleven of eleven general and technical supervisors for calendar year 2018.
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 reviewing the April 2019 temperature and humidity log book located in the New Born Screening test area and confirmation by a testing personnel, the laboratory failed to take corrective action when the humidity of the room in which testing takes place went below the required acceptable range of 15 to 60% as indicated in the log

	book. The humidity was recorded as "Lo", meaning below the lower threshold of 15% on April 6, 7, 8, 12, and 13.
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 review of the Individualized Quality Control Plan (IQCP) of Cepheid Gene Expert Assay for Mtb/Rifampin and interview with the Program Manager and QA Officer, the Quality Control Plan (QCP) step of the IQCP did not have the signed approval of the laboratory director. The laboratory director, QA officer and Program Manager affixed their signature on the IQCP itself on 12/18/2019.