Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660818	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
City Of El Paso Department Of Public Health	9566 Railroad Dr, El Paso, TX	

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
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observations, review of maintenance records, policies and procedures and interview of facility personnel, the laboratory failed to have a unidirectional workflow for PCR testing and a procedure to monitor and prevent contamination. Findings included: 1. Observations made during the tour of the facility found that the laboratory performed each stage of testing in separate rooms, traveling through the same hallway between steps in the testing procedure. a. The raw specimens contained in Viral transport medium were received in the Food Lab. Accessioning of the specimens was done on the last counter of the food lab. They were then stored in the food lab refrigerator until testing begins. b. Specimens were brought from the food lab refrigerator, down the hallway to the BSL3 room for extraction. Once the extraction process was complete, they were placed in the refrigerator of the BSL3 room. c. The Tech would then exit the BSL3 room and go down the hallway to the Dust Free Room where reagents were prepared. d. The tech would leave the Dust Free Room and return to the BSL 3 room to obtain specimens. e. Specimens were then brought down the hallway to the Food lab hood on the first counter for reagent addition and covering of the plates. f. Plates were then taken from the food lab down the hallway to the Bio-watch lab for testing. 2. Review of maintenance records found no documentation of wipe tests of areas were amplification procedures were employed. 3. Review of the CDC procedure for Influenza found on page 11 bullet 3_ " Amplification technologies such as PCR are sensitive to accidental introduction of product from previous amplifications reactions. Incorrect results could occur if either the clinical specimen or the real-time reagents used in the amplification step become contaminated by

	accidental introduction of amplification product (amplicon). Workflow in the laboratory should proceed in a unidirectional workflow>" 4. Interview of testing personnel conducted on July 24, 2018 at 2:49 PM confirmed that the laboratory did not perform wipe tests of areas where amplification procedures were done to detect and prevent contamination of PCR testing, and that the laboratory did not have a unidirectional workflow.
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 operator's manual for the Hologic Gen-Probe Panther, review of environmental records, and interview with facility personnel, the laboratory failed to monitor the humidity operating requirements for the analyzer for 11 of 11 days between July 9th, 2018 and July 24th, 2018. The findings included: 1. Based on review of the Hologic Gen-Probe Panther, under Specifications and Requirements, the operator's manual states the following: "Environmental Requirements Relative Humidity Operating: 20 - 85% non-condensing." 2. Based on review of laboratory environmental records, the laboratory recorded eleven (11) operating temperatures between July 9th, 2018 and July 24th. The laboratory did not record humidity levels during the 11 of 11 measurements. 3. In an interview at 14:00 hours in the Panther room, the General Supervisor stated the laboratory had recently become aware of the humidity requirement but had not been able to order the proper monitoring devices.