Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2183961	09/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
City Of El Paso Dept Of Public Health Lab	500 W University Ave, 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
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780. D6076 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
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 review of manufacturer's instructions, policies and procedures,maintenance procedures and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to monitor and prevent contamination when using the Hologic Aptima SARS-COV-2 Assay (Panther System) between June 2020 and September 2020. Findings included: 1. Review of the manufacturer's instructions for the Hologic Aptima SARS-COV-2 Assay (Panther System) (AWW-2149-001 rev. 002) found on page 14 D. Lab contamination monitoring protocol for the Panther system There are many laboratory specific factors that may contribute to contamination, including testing volume, workflow, disease prevalence and various other laboratory activities. These factors should be taken into consideration when contamination monitoring frequencies being established. Intervals for contamination monitoring should be established based on each laboratory's practices and procedures. 2. A review of the laboratory's own policy titled Aptima SARS-COV-2 Assay (Panther System) dated July 16, 2020 found: on page 16 of 21:" The Laboratory will monitor for contamination is part of routine QC. Results will be documented into the tests QC/maintenance logs. Corrective actions (if any) will be documented on corrective action forms. To monitor for laboratory contamination, the following procedure may be performed using the Aptima Multitest Swab Specimen Collection

	Kit." 3. Review of maintenance records found no documentation of wipe tests of areas where Aptima SARS-COV-2 Assay (Panther System) were conducted. 4. Interview of the technical supervisor conducted on September 24, 2020 confirmed that the laboratory did not perform wipe tests of areas where SARS-COV-2 procedures were done to detect and prevent contamination of PCR testing, and that the laboratory did not have a unidirectional workflow.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, policies and procedures,maintenance procedures and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to monitor and prevent contamination when using the Hologic Aptima SARS-COV-2 Assay (Panther System) between June 2020 and September 2020. (See D 3005)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observations, review of manufacturer's instructions, review of policies and procedures, personnel records, patient test records, maintenance procedures and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for ensuring all testing personnel using the SARS-CoV-2 Assay (Panther system) have documented training, failed to perform procedures to monitor and prevent contamination of the area were testing was done and stored previously tested patient specimens according to the manufacturer's instructions. Findings included: 1. Observations made during the tour of the facility found that the laboratory stored 21 previously tested specimens (collected between July 14, 2020 and July 18, 2020) under the cabinet without covering these specimens tubes with a new covering. 2. Review of the manufacturer's instructions found: a. On page 4 under the heading Warnings and Precautions "B. Only personnel adequately trained on the use of this assay and in handling potentially infectious materials should perform these procedures. D. Specimens may be infectious. Use universal precautions when performing this assay. Proper handling and disposal methods should be established by the laboratory director. Only personnel adequately trained in handling infectious materials should be permitted to perform this diagnostic procedure." b. On page 4 under the heading Warnings and Precautions "L. Avoid cross contamination during the specimen handling steps. Specimens can contain extremely high levels of virus or other organisms. Ensure that specimen containers do not come in contact with one another, and discard used materials without passing them over any open containers.

	Change gloves if they come in contact with specimens." c. On page 7 under the heading Storing Samples after Testing "1. Samples that have been SHB stored upright in the rack under the following condition: 2C to 30C for up to six days 2. The sample should be covered with a new, clean plastic film or foil barrier." d. On page 14 Under the Heading Procedural Notes: "D. Lab Contamination Monitoring Protocol for the Panther System there are many laboratory specific factors that may contribute to contamination, including testing volume, workflow, disease prevalence and various other laboratory activities these factors should be taken into consideration when contamination monitoring frequency is being established intervals for contamination monitoring should be established based on each laboratory's practices and procedures." 3. Review of the laboratory's own procedure titled Aptima SARS-CoV-2 Assay (Panther system) found: a. On page 4 of 21 under the heading Specimen Transport and Storage "samples that have been tested can be kept at 2C to 30C up to six days samples should be covered with a clean, plastic film or foil barrier." b. On page 7 of 21 under the heading Maintenance - the laboratory failed to define a procedure for performing wipe test to monitor and prevent contamination of laboratory areas used for testing patientsspecimens for SARS CoV- 2 assay (Panther system). 4. Review of patient test records found the laboratory tested 1165 patients between June 24, 2020 and August 16, 2020. No patient testing had been done at this laboratory due to lack of personnel. Interview the technical supervisor conducted on September 22, 2020 at 10:25 AM confirmed that the laboratory last tested specimens "approximately one month ago or more ". Interview of the technical supervisor conducted on September 24, 2020 confirmed: a. At 8:47 PM - the laboratory had no documentation of training for seven of seven testing personnel performing the SARS CoV- 2 assay (Panther system) testing. b. At 9:57 AM -The laboratory did not perform wipe tests of areas where SARS CoV-2 tests were done to detect and prevent contamination of PCR testing, and that the laboratory did not have a unidirectional workflow. c. At 10:21 AM - the laboratory did not follow the manufacturer's instructions for the storage of previously tested patient specimens.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures and interview of facility personnel found the laboratory failed to have a written policy to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283. 1. The laboratory failed to ensure that previously tested patient specimens were stored as specified in the manufacturers instructions for use, and that testing personnel received the appropriate training prior to using the SARS-CoV-2 Assay (Panther system) for testing patient specimens. (See D5411)
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance

	with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to provide overall management and direction to the laboratory. (See D6087, D6088, D6094, D6101, and D6106)
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions,verification records, and interview a facility personnel, the laboratory director failed to ensure testing personnel were performing test procedures as instructed by the manufacturer when using the Hologic Aptima SARS-COV-2 Assay (Panther System).(See D3005 and D5411)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions,verification records, and interview a facility personnel, the laboratory director failed to establish and maintain a quality assurance program for COVID 19 testing using the Aptima SARS-CoV-2 Assay (Panther system). (See D5391 and D 5791)
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, patient test records and staff interview, it was revealed the laboratory director failed to ensure the laboratory had enough testing personnel with adequate training to perdorm SARS CoV-2 testing using the Aptima SARS CoV-2 (Panther System) for testing patients specimens. The findings included: 1. Review of Personnel found documentation of training for seven of seven testing personnel using the Aptima SARS CoV-2 (Panther System) . 2. Interview of the technical supervisor conducted on September 22, 2020 at 10:25 AM confirmed that "we did not

	have enough testing personnel to staff this laboratory as well as the other laboratory." He went on to confirm that documented training was not available for seven of seven testing personnel using the Aptima SARS CoV-2 (Panther System) .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, patient test records and staff interview, it was revealed the laboratory director failed to ensure that seven of seven testing personnel had documentation training to perform high complexity testing using the Aptima SARS CoV-2 (Panther System). (See D5411)