Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660818	06/29/2021
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
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: 493. 801 Condition: Enrollment and testing of samples 493. 1441 Condition: Laboratories Performing High Complexity Testing; Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory testing records, CMS report 155, and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for Mycobacteriology in 2021. The findings included: 1. A review of facility proficiency testing records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Mycobacteriology 2021. 2. Review of patient test records found the laboratory tested 212 patient specimens for Mycobacteriology using the Quantiferon TB Gold test between January 1, 2021 and June 29, 2021 3. Review of the CMS report 155 found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 4. Interview of the Lead Medical Lab Scientist conducted on June 29, 2021 at 08:47 AM confirmed that the laboratory did not enroll in, or participate in a proficiency testing program for Mycobacteriology in 2021.

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: Review of the CMS form 209 Laboratory Personnel Report, policies and procedures, personnel files and interview of facility personnel found that the laboratory failed to have a procedure to assess the competency of all testing personnel , supervisors and consultants performing Quantiferon Gold Tuberculosis (TB) procedures in 2019, 2020 or 2021. THIS IS A REPEAT DEFICIENCY FROM THE 02/2012 INSPECTION The findings included: 1. Review of the CMS 209 Laboratory Personnel Report found the Laboratory Listed five Testing Personnel, one Technical Supervisor, one Clinical Consultant and one general supervisor performing Quantiferon Gold Tuberculosis (TB) procedures. 2. Review of policies and procedures found on page 2 of the policy titled Quality Management program under the heading procedure - "All new employees will receive formal orientation and training in all areas of responsibility and must demonstrate competency before being allowed to work independently. Competency is assessed within the first 6 months of hire and annually thereafter for all employees". 3 . Competency assessment records for all personnel were requested on June 29, 2021 at 09:38 AM. There were no competency assessment records available for review as follows: a. Testing person one had no competency assessments available for review to ensure his competency was assessed in 2019, 2020, or 2021. b. Testing person one was also designated as the technical supervisor and the general supervisor(effective March 2020). c. No semiannual competency assessments were available for review for testing person 3 (hired 01/06/2020) There were no competency assessments available for review to ensure the technical supervisor and the general supervisor had been evaluated and deemed competent for the responsibilities of their positions. 4. Interview of the lead Medical Lab Scientist conducted June 29, 2021 at 10:27 AM confirmed that competency assessments for testing person one and the technical consultant were not available for review.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel, the laboratory failed to have a quality assessment program to identify and correct problems in general Lab systems. THIS IS A REPEAT DEFICIENCY FROM THE 08 /2016 INSPECTION The laboratory failed to enroll in a proficiency testing program for Gram Stain and Syphilis Serology in 2021. (See D 2000) The laboratory failed to have a procedure to assess all testing personnel, consultants and supervisors. (See D 5209)

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: Review of personnel files, laboratory records, quality control records and interview of facility personnel found the laboratory director failed to provide overall management and technical direction. Findings Included: 1. The laboratory Director failed to notify the state agency when testing for subspecialties and specilties were removed from the testing offered. 2. The laboratory director failed to ensure that they laboratory was enrolled in an HHS approved proficiency testing program for each specialty and subspecialty tested by the laboratory. (See D6088) 3. The laboratory director failed to ensure that the quality assessment programs had been established and maintained to assure the quality of laboratory testing. (See D6094) 4.The laboratory director failed to ensure that policies and procedures were established for monitoring the performance and competency of testing personnel, supervisors and consultants. (See D6103)
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Review of proficiency testing records, patient test records and interview of facility personnel found the laboratory director failed to ensure the laboratory was enrolled in a CMS approved proficiency testing program for Mycobacteriology in 2021.
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 Mycobacteriology (See D5291) tHIS IS A REPEAT DEFICIENCY FROM THE 08/2016 INSPECTION
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: Review of the CMS report 209, personnel records and interview of facility personnel found the laboratory director failed to ensure that the procedure used to assess the competency of personnel included the assessment of all testing personnel, supervisors, and consultants. (see D5209)
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Review of the CMS form 209 Laboratory Personnel Report, policies and procedures, personnel files and interview of facility personnel found that the Technical supervisor failed to assess the competency of all testing personnel , supervisors and consultants performing Quantiferon Gold Tuberculosis (TB) procedures in 2019, 2020 or 2021. The findings included: 1. Review of the CMS 209 Laboratory Personnel Report found the Laboratory Listed five Testing Personnel, one Technical Supervisor, one Clinical Consultant and one general supervisor performing Quantiferon Gold Tuberculosis (TB) procedures. 2. Review of policies and procedures found on page 2 of the policy titled Quality Management program under the heading procedure - "All new employees will receive formal orientation and training in all areas of responsibility and must demonstrate competency before being allowed to work independently. Competency is assessed within the first 6 months of hire and annually thereafter for all employees". 3 . Competency assessment records for all personnel were requested on June 29, 2021 at 09:38 AM. There were no competency assessment records available for review as follows: a. Testing person one had no competency assessments available for review to ensure his competency was assessed in 2019, 2020, or 2021. b. Testing person one was also designated as the technical supervisor and the general supervisor(effective March 2020). c. No semiannual competency assessments were available for review for testing person 3 (hired 01/06/2020) 4. Interview of the lead Medical Lab Scientist conducted June 29, 2021 at 10:27 AM confirmed that competency assessments for testing person one and semiannual competency assessments for testing person three were not available for review.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Review of the CMS form 209 Laboratory Personnel Report, policies and procedures, personnel files and interview of facility personnel found that the Technical supervisor failed to assess the competency of all testing personnel , supervisors and consultants performing Quantiferon Gold Tuberculosis (TB) procedures at least annually in 2019, 2020 or 2021. The findings included: 1. Review of the CMS 209 Laboratory Personnel Report found the Laboratory Listed five Testing Personnel, one Technical Supervisor, one Clinical Consultant and one general supervisor performing Quantiferon Gold Tuberculosis (TB) procedures. 2. Review of policies and procedures found on page 2 of the policy titled Quality Management program under the heading procedure - "All new employees will receive formal orientation and training in all areas of responsibility and must demonstrate competency before being allowed to work independently. Competency is assessed within the first 6 months of hire and annually thereafter for all employees". 3 . Competency assessment records for all personnel were requested on June 29, 2021 at 09:38 AM. There were no competency assessment records available for review as follows: a. Testing person one (hired 08/16 /2016) had no competency assessments available for review to ensure his competency was assessed in 2019, 2020, or 2021. b. Testing person one was also designated as the technical supervisor and the general supervisor (effective March 2020), with no competency assessments available for review for the responsibilities of those positions. c. No competency assessment performed in 2019, 2020, or 2021 available for review for testing person 2 (hired 10/23/2006). d. No competency assessment was available for review for the clinical consultant. 4. Interview of the lead Medical Lab Scientist conducted June 29, 2021 at 10:27 AM confirmed that competency assessments were not available for review.