Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660818	08/03/2022
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
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: Review of the manufacturer's instructions, CMS 116, patient reports and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions for disseminating all authorized fact sheets when using the CDC Influenza SARS-CoV-2(Flu SC2) Multiplex Assay as defined in the Conditions of Authorization for Use. The findings included: 1. Review of the manufacturer's instructions found on page 33 under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using your product must include with the test result reports,all authorized Fact Sheets." 2. Review of the CMS 116 found the laboratory recorded an annual volume of 6344 SARS- COV-2 tests performed. 3. Review of patient reports found the laboratory did not include instructions to providers on where to obtain the fact sheets or included copies of the authorized fact sheets. 4. Interview of the General Supervisor on the CMS report 209 Laboratory Personnel Report conducted August 3, 2022 at 09:22 AM confirmed that the laboratory did not include the authorized Fact Sheets with the patient test results for SARS COV-2 using the CDC Influenza SARS-CoV-2(Flu SC2) Multiplex Assay as defined in the Conditions of Authorization for Use.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative

	mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. This STANDARD is not met as evidenced by: Review of the manufacturers instructions for use for the QuantiFERON-TB GOLD PLUS (QFT_PLUs) ELISA, the laboratory's own written procedure, patient test records and interview of facility personnel found the laboratory failed to determine the appropriate control materials and frequency of testing control materials when testing patient specimens for tuberculosis. The findings included: 1. Review of the manufacturers instructions for the QuantiFERON-TB GOLD PLUS (QFT_PLUS) ELISA found on page 34 found: " Each laboratory should determine appropriate types of control materials and frequency of testing in accordance with Local, State, Federal, or other applicable accrediting organizations. External quality assessment and alternative validation procedures should be considered. Note: Plasmas spiked with recombinant IFN-y have shown reductions of up to 50% in concentration when stored at either 2C to 8C and 20C." 2. Review of the laboratory's own written policy found on page 19:" Each laboratory should determine appropriate types of control materials and frequency of testing in accordance with Local, State, Federal, or other applicable accrediting organizations. External quality assessment and alternative validation procedures should be considered. Note: Plasmas spiked with recombinant IFN-y have shown reductions of up to 50% in concentration when stored at either 2C to 8C and 20C. A known negative sample and a known positive sample will be used as alternate quality control since a commercial control is not available." 3. Review of patient test records found the laboratory tested 124 specimens for tuberculosis using the QuantiFERON-TB GOLD PLUS (QFT_PLUS) ELSA between April 1, 2022 and June 30 2022, without using a known positive and negative sample as external quality controls. 4. Interview of testing personnel conducted August 3, 2022 confirmed it was the laboratory's procedure to use previously tested specimens as positive and negative quality control materials which were frozen for future use. After the move to the new location in March of 2022, it was noted these specimens may have been compromised and were not producing results as expected. The laboratory contacted the manufacturer and were informed they could meet the quality control requirements using a standard from the previously used kit, but did not state the lot number needed to be different from the lot number in use.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Review of the CMS 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory director failed to specify in writing the duties and responsibilities for eight of eight testing personnel, and the procedures they were authorized to perform. The findings included: 1. Review of the

	CMS report 209 Laboratory Personnel Report found the laboratory designated eight testing personnel performing high complexity testing. 2. Review of personnel files found no written authorization of procedures for each of the eight testing personnel. 3, Interview of the General Supervisor conducted August 2, 2022 at 10:10 AM confirmed the laboratory did not have a written delegation of duties for each testing person to define which procedures they were authorized to perform.