

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2189001	(X3) Date Survey Completed 09/23/2020
Name of Provider or Supplier University Of Texas At El Paso, The	Street Address, City, State 751 Electric Rd, 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	An unannounced complaint investigation TX00358479 was conducted on site from 09/22-9/23/2020. Complaint TX00358479 is not substantiated
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and staff interview, it was revealed the laboratory director failed to ensure the facility had a written quality control plan. The findings were: 1. A review of the laboratory's policies and procedures revealed the laboratory did not have a written quality control plan. 2. The laboratory was asked to provide documentation of having a quality control plan. No documentation was provided. 3. An interview with testing personnel number 6 (as listed on Form CMS 209) on 09/23/2020 at 1035 hours in the conference room revealed the laboratory did not have a quality control plan. This confirmed the findings.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's policies and procedures, and staff interview, it was revealed the laboratory director failed to ensure the facility had a written quality assurance plan. The findings were: 1. A review of the laboratory's policies and procedures revealed the laboratory did not have a written quality assurance plan. 2. The laboratory was asked to provide documentation of having a quality assurance plan. No documentation was provided. 3. An interview with testing personnel number 6 (as listed on Form CMS 209) on 09/23/2020 at 1035 hours in the conference room revealed the laboratory did not have a quality assurance plan. This confirmed the findings.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

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, and staff interview, it was revealed the laboratory director failed to ensure testing personnel had documentation of training prior to performing patient testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 09/22/2020) revealed the laboratory identified 8 testing personnel who performed COVID-19 testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 5 of 8 personnel performing COVID-19 testing. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 2 Testing personnel number 3 Testing personnel number 4 Testing personnel number 5 3. The facility was asked to provide documentation of training occurring prior to the identified personnel performing patient testing. No documentation was provided. 4. An interview with testing personnel number 6 (as listed on Form CMS 209) revealed the laboratory did not have documentation of training occurring prior to testing being performed. This confirmed the findings.