Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2182351	04/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pro Lab Diagnostics Inc	1301 Blue Ridge Dr, Georgetown, 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	Based on an onsite complaint investigation conducted 3/31/2021 and 4/1/2021, the complaint was substantiated. TX00377326
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with facility staff, the laboratory failed to ensure the Quality Assessment procedures were approved, signed, or dated by the laboratory director before use. Findings included: 1. Based on review of laboratory procedures, the laboratory Quality Assessment procedure heading stated the following: "Document number/version.... Subject..... Department...Written by: {name of Testing Person 8 from CMS 209}...Reviewed and approved by.....Date of original.....Date of revision....Date retired...." The laboratory policy was not approved, signed and dated by the laboratory director. 2. During an interview at 09:51 hours on 4/1/2021 in the facility office, the Supervisor confirmed the previous laboratory director had not formally approved, signed, and dated the Quality Assessment procedure. On 4/1/2021, the current laboratory director approved, signed, and dated the Quality Assessment policy, prior to the exit conference.
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 CMS 209 Laboratory Personnel Report form, the laboratory's personnel records, and interview with facility staff, the laboratory director failed to ensure 1 of 8 testing personnel had documentation of training to perform high complexity testing prior to testing patients' specimens. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 4/1/2021) revealed the laboratory identified 8 testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed testing person #7 (as indicated on the CMS 209 form) failed to have documentation of training for performing high complexity testing. In the personnel file, Testing Person 7 had a form titled "Pro-AmpRT SARS-Cov-2 Training Checklist". The form was initialed by Testing Person 2 and signed by Testing Person 2 beside the field "Trainer signature". The column with titled "Initials Trainee" was blank and all of the "date" cells were blank. 3. In an interview at 15:02 hours on 3/31/2021 in the office, when asked if the laboratory had other training for Testing Person 7 prior to performing patient testing, the Supervisor stated "no, that should have been done."