Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2192790	02/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Adx Diagnostic Lab	6009 Richmond Avenue Suite 130, Houston, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 surveyor observation, review of the laboratory's policies and maintenance records, and staff interview, it was revealed that the laboratory failed to have a unidirectional workflow for PCR testing using the Assurance SARS-COV-2 Panel test system to ensure contamination prevention of patient specimens, equipment, and supplies. Findings include: 1. Surveyor observation of the laboratory on 2/28/22 at 11: 00 a.m. revealed the pre-amplification and the post-amplification areas were located within the main laboratory. There was a large metal table where patient samples were accessioned positioned along the right wall of the laboratory, a hood for pipetting patient samples and reagents onto the test plates along the left wall of the laboratory,

	the BioRad CFX96 analyzer positioned on another metal table at the front wall of the laboratory, and a large biohazard bag for the disposal of amplified test plates between the BioRad CFX96 analyzer and the metal table where patient samples are accessioned. 2. A review of the laboratory's policy titled 'Extraction Free Direct PCR of SARS-COV-2' revealed the policy did not include actions to take to ensure a unidirectional workflow or how to avoid contamination. 3. A review of the laboratory's maintenance records found no documentation of wipe tests of areas where the Assurance SARS-COV-2 Panel tests were performed. 4. A review of the laboratory's submitted CMS 116 form revealed the laboratory estimated performing 5000 PCR tests using the Assurance SARS-COV-2 Panel test system. 5. An interview with the laboratory director on 2/28/22 at 2:00 p.m. in the office area, after review of the records, confirmed the above 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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the laboratory director failed to ensure documentation of training for 2 of 3 testing personnel performing high complexity testing using the Assurance SARS-COV-2 Panel test system. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 2/25/22) revealed the the laboratory identified 3 testing person performing high complexity testing. 2. A review of the laboratory's personnel records revealed the following testing personnel had no documentation of training prior to testing patient's specimens using the Assurance SARS-COV-2 Panel test system: Testing person #2 Testing person #3 3. An interview with the laboratory director on 2 /28/22 at 1:45 p.m. in the office area, after review of the records, confirmed the above testing.