Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2234510	06/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Aza Labs Inc	4801 W Peterson Ave #204, Chicago, IL	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: The surveyor's review of the manufacturers' instructions for use, direct observation, and an interview with the general supervisor (GS) revealed the laboratory failed to meet the requirements of this condition. The laboratory failed to provide a unidirectional workflow for molecular amplification procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies. (Refer to D3005).
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:

	The surveyor's review of the manufacturers' instructions for use, direct observation, and an interview with the general supervisor (GS) revealed the laboratory failed to maintain a uni-directional workflow for molecular amplification procedures to prevent potential cross-contamination in specimen processing, preparation, amplification, and detection for SARS-CoV-2. (Affecting a total of 138,485 patient tests results for two of two testing years; 2022 and 2023.) Findings Include: 1. Review of the instructions for use for the lumiraDx SARS - COV- 2 RNA STAR Complete Section 9.2, "Specimen Preparation & Plate Set-Up" revealed the following: a. "1. Maintain separate areas for assay setup and handling of clinical specimens." b. "4. Maintain separate, dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips) for assay setup and handling of clinical specimens." c. "NOTE: Please handle the Pos. Ctrl. Med. with care as it can cause false positives if accidentally spilled or handled carelessly. To avoid cross-contamination, handle the positive control material in areas different from the area in which the patient handling is performed, and use separate pipette tips for all materials." 2. Direct observation on 06/22/2023 at 11:57 a.m., of the GS demonstrating the testing procedures for the lumiraDx SARS - COV- 2 RNA STAR Complete (LDX) assay revealed the following: a. The GS performed the testing process all within the same biological safety cabinet. The process demonstrated included the following; the preparation of salt mix and master mix reagents, the transfer of patient samples, and the addition of positive and negative control samples to the patient testing plates. ("Labculture-RELIANT class II, Type A2"). b. Used LDX positive control sample vials and patient samples were stored in the same refrigerator. ("GE Quality TFX25JR TFX22JR"). c. The GS used the same pipette for the transfer of patient samples and the addition of positive and negative control samples to the patient testing plates. ("OXFORD LAB PRODUCTS USA 20 - 200 mL") 3. On 06/22 /2023, at 12:15 p.m., the GS confirmed the above findings.