Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2253709	03/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Illinios Tech Labs Inc	9150 Crawford Ave - Ste 104, Skokie, 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
D3005	FACILITIES CFR(s): 493.1101(a)(3) (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's direct observation, review of laboratory records, and interview with the general supervisor (GS), 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 of one of one virology analyte, SARS-CoV-2 (Covid) from January 2022 through May 2023 affecting 41,068 patient tests. Findings include: 1. Review of the "LumiraDx SARS-CoV-2 RNA STAR Complete - Instructions for Use" revealed the following information. a) "9 LumiraDx SARS-CoV-2 RNA STAR Complete Preparation ...9.2 Specimen Preparation & Plate Set-Up ...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. NOTE: Amplification technologies such as qSTAR, like PCR, are sensitive to accidental introduction of product from previous amplification reactions. Incorrect results could occur if either the clinical specimen or the qSTAR reagents used in the amplification step become contaminated by accidental introduction of amplification product (amplicon). Workflow in the laboratory should always proceed in a unidirectional manner to minimize such contamination events." 2. On 03/28/2025, at 9:58 a.m., direct observation during a laboratory tour with the GS revealed the laboratory failed to maintain a uni-directional workflow for the molecular amplification of SARS-CoV-2: a) The transfer of patient samples to the patient testing

	plates and the addition of positive and negative control samples to the patient testing plates all performed in one biosafety cabinet (BSC) "Mystaire SN: MYPCR321-2212" utilizing one set of pipettes. 3. On 03/28/2025, at 1:00 p.m., the GS confirmed the 41,068 patient tests recorded on the "Laboratory Non-waived CLIA Tests Volumes Work Sheet" were conducted in the same BSC with one set of pipettes.