Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2257061	04/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Optima Clinical Lab	4539 N Sheridan Rd, 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: Based on surveyor's direct observation, laboratory documentation, and interview with the general supervisor (GS); 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: Based on surveyor's direct observation, laboratory documentation, 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 for SARS-CoV-2, influenza A and influenza B in 2022 through date of survey 04/05 /2024. Affecting more than 12,285 patient tests. Findings Include: 1. Review of the manufacturer's "TaqPath COVID-19, FluA, FluB Combo Kit INSTRUCTIONS FOR USE" stated the following information: "Warnings and precautions The TaqPath COVID-19, FluA, FluB Combo Kit workflow should be performed by qualified and trained staff to avoid the risk of erroneous results. Use separate areas for the preparation of patient samples and controls to prevent false positive results. Samples and reagents must be handled in a biological safety cabinet." 2. On 04/05/2024 at 9:30 a.m., direct observation of the GS demonstrating the testing procedures for the "TaqPath COVID-19, FluA, FluB Combo Kit" assay revealed the laboratory failed to follow the general warnings and precautions outlined in the manufacturer's instructions for use in 2022 through date of survey 04/05/2024. Affecting more than 12,285 patient tests. a. The preparation of extraction buffer reagent, 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 ("ACROSS INTERNATIONAL, Model: BC-2F. Serial Number: BSC70A211200320A"). b. One set of pipettes utilized for the preparation of extraction reagents, the transfer of patient samples to the patient testing plates, and the addition of positive and negative control samples to the patient testing plates. c. The testing pipettes stored on a rack outside of the biosafety cabinet. 3. Direct observation on 04/05/2024 at 9:42 a.m., revealed the transportation of the positive control to biosafety cabinet, "Serial Number: BSC70A211200320A", for addition to patient sample plates. 4. On 04/05/2024 at 9:54 a.m., the GS confirmed the above findings.