

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2250299	(X3) Date Survey Completed 12/15/2023
Name of Provider or Supplier Rapid Healthcare Laboratory Llc	Street Address, City, State 881 E Chicago St - 2nd Flr, Elgin, 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	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>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.</p> <p>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).</p>
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's direct observation, manufacturers' instructions for use, laboratory</p>

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 for SARS-CoV-2, Influenza A and Influenza B for two of two testing years (2022 and 2023). Findings Include: 1. Review of the "TaqPath COVID-19, FluA, FluB (TPCIA/B) Combo Kit INSTRUCTIONS FOR USE" revealed the following: a. "INTENDED USE: The TaqPath COVID-19, FluA, FluB Combo Kit is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures." b. "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 12/14/2023, at 10:45 a.m., direct observation of the GS demonstrating the testing procedures for the "TaqPath COVID-19, FluA, FluB Combo Kit" (TPCIA/B) assay revealed the following: a) preparation of patient samples and extraction buffer reagents performed on a benchtop outside of the biological safety cabinet; b) extracted patient samples vortexed and transferred to patient testing plates; addition of positive and negative control samples to the patient testing plates, all performed utilizing the same pipettes in one biosafety cabinet ("ACROSS International Serial No. NA6FAT220300006A"). 3. On 12/14/2023, at 10:45 a.m., an interview with the GS confirmed the above findings.