Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2237799	07/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Align Laboratories Llc	3926 Barron St, Suite C107, Metairie, LA	

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
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: A Follow-up survey was performed at Align Laboratories, LLC, CLIA # 19D2237799, on July 27, 2023 through July 31, 2023. Findings: Based on review of patient final reports, performance verification studies, and interview with personnel, the laboratory failed to ensure results for the antibiotic resistance gene (ABG) panel for the respiratory pathogen panel (RPP) were transmitted by the laboratory information system (LIS) accurately. Findings: 1. Review of the laboratory's performance specification studies for RPP and ABR testing revealed the laboratory did not validate the test system to report Sulfonamides. 2. Review of the following two (2) patient final test reports revealed the laboratory reported incorrect results: a) Patient RC231390012: Result for Sulfonamides was reported and discrepancy between instrument and final report results for Tetracycline. The instrument result indicated Tetracycline was "detected" (resistant), while the final report indicated "Not Detected" (non-resistant). b) Patient RC231390013: Result for Sulfonamides was reported 3. In interview on July 31, 2023, the Technical Supervisor stated she was unaware that Sulfonamides results were being reported. The Technical Supervisor confirmed the laboratory did not ensure the correct drugs and results were transmitted accurately by the laboratory's LIS.

D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: A Follow-up survey was performed at Align Laboratories, LLC, CLIA # 19D2237799, on July 27, 2023 through July 31, 2023. Based on review of the laboratory's personnel records and interview with personnel, the Technical Supervisor failed to ensure performance of a semi-annual competency assessment for Urinary Tract Infection (UTI) testing as required for two (2) of two (2) testing personnel reviewed. Findings: 1. Review of personnel records revealed the initial training for UTI testing for the Technical Supervisor (also serves as Testing Personnel) and Testing Personnel 1 were performed on October 7, 2022. 2. Further review of personnel records for the Technical Supervisor and Testing Personnel 1 revealed semi-annual competency assessments for UTI testing, due April 2023, were not performed. 3. In interview on July 31, 2023 at 9:43 am, the Technical Supervisor confirmed semi-annual competency assessments for UTI testing were not performed for the identified personnel.