Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2042184	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lab Express Corporation	5000 W 95th St, Oak Lawn, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical consultant (TC), the laboratory failed to have available written procedures for the testing of 2 of 39 chemistry analytes (Potassium (K)) and Sodium (Na)) listed on the "Lab Express Corporation...Non Waived Test List" affecting over 20,116 tests. Findings include: 1. Review of the "Lab Express Corporation...Non Waived Test List" revealed 39 chemistry analytes utilized for patient testing. Albumin, Alkaline phosphatase, Alanine transaminase, Aspartate aminotransferase, Total carbon dioxide, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Cholesterol, Creatinine, Urine Creatinine, C - Reactive Protein, Glucose, Hemoglobin A1C, High - Density Lipoprotein cholesterol, Iron, Low - Density Lipoprotein cholesterol, Magnesium, Phosphorous, Total Protein, Urine Protein, Potassium, Recombinant Human C - Reactive Protein, Sodium, Total Iron-Binding Capacity, Triglyceride, Urea Nitrogen, Uric Acid, Vancomycin, Valproic Acid, Ferritin, Folate, Free T4, Free T3, Total Prostate-Specific Antigen, Thyroid-stimulating hormone, Vitamin B12, and Vitamin D 2. Review of the laboratory's procedure manual revealed the laboratory failed to make available written procedures for the testing of 2 of 39 chemistry analytes, K and Na. 3. Review of patient test records documented 20,116 patient tests were performed for K and Na from January 2024 to January 2025. 4. On 01/14/2025, the TC confirmed the lab failed to have procedures available for testing K and Na.
D5403	PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation and interview with the technical consultant (TC), the laboratory's procedure manual failed to include the required elements for chemistry and hematology analyte testing, affecting over 204,212 tests. Findings include: 1. Review of the "Lab Express Corporation Oak Lawn, Illinois" procedure manual revealed the laboratory failed to include the following elements for moderate complexity chemistry and hematology analyte testing: a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; b) Step-by-step performance of the procedure, including test calculations and interpretation of results; c) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing; d) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. 2. Review of laboratory records revealed 204,212 patient tests were performed from January 2024 to January 2025 for the specialties of hematology and chemistry. 3. On 01/14/2025, the TC confirmed the lab failed to have all the required procedures for testing chemistry and hematology.