Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2089973	03/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Tulsa Hills	7858 S Olympia Ave, Tulsa, OK	

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
D0000	The recertification survey was performed on 03/27/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director the laboratory failed to ensure one of one Vacutainer brand tubes were stored as required by the manufacturer in the laboratory freezer. Findings include: (1) Observation of the laboratory freezer and interview with the laboratory director on 03/27/2024 at 10:38 am, identified the following: (a) One Vacutainer K2, EDTA tube, lot # 2321370, storage temperature of 4-25 degrees Celsius. (2) Interview with the laboratory director on 03/27/2024 at 10:38 am confirmed the tube was being stored below the manufacterer's stated temperature.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory director, the laboratory failed to ensure iSTAT cartridges had not exceeded their room temperature expiration date for one of four cartridge types observed. Findings include: CHEM 8+ (1) On 03/27/2024 at 11:30 am, the laboratory director stated Chem8+ (Na, Cl, Glucose, K, BUN, Creatinine, Ionized Calcium, and TCO2) testing was performed using the Chem8+ cartridge and the iSTAT 1 analyzer; (2) Observation of the laboratory on 03/27/2024 at 11:30 am identified five Chem8+ cartridges stored at room temperature (Lot #H24007), without documentation of when they were removed from refrigeration; (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for 14 days. TROPONIN I (1) On 03/27/2024 at 1130 am, the laboratory director stated troponin testing was performed using the cTnI cartridge and the iSTAT 1 analyzer; (2) Observation of the laboratory on 03/27/2024 at 11:30 am identified two cTnI cartridges stored at room temperature (Lot #B23249A), without documentation of when they were removed from refrigeration. (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for 14 days. (4) Interview with the laboratory manager on 03/27/2024 at 11:42 am confirmed the cartridges had been placed at room temperature without any way to monitor if they exceeded the manufacturer's room temperature expiration date.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to verify the stated values of control materials before they were put into use for nine of nine lot numbers. Findings include: (1) On 03/27/2024 at 11:30 am, the laboratory director stated the following: (a) CBC (Complete Blood Count) testing was performed using the Beckman Coulter DxH 520 analyzer; (b) Three levels of QC (quality control) materials were tested daily; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records identified no evidence the provided ranges were verified before the lot numbers were

	put into use for nine of nine lot numbers as follows: (a) Low control lot #362317911, Normal control lot #362314912, and High control lot #372314913 put into use on 08 /05/2023; (b) Low control lot #3523115111, Normal control lot #362315112, and High control lot #372315113put into use on 10/06/2023. (c) Low control lot #3523114711, Normal control lot #362314712, and High control lot #372314713 put into use on 06/06/2023. (3) The findings were reviewed with the laboratory director who stated on 03/27/2024 at 12:00 pm, the manufacturer's ranges had not been verified before the above lot numbers had been put into use.