Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475385	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Warren Clinic Mcalester	1401 East Van Buren, Mcalester, 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 03/26/19. The findings were reviewed with the laboratory technical services manager and the technical consultant/clinic supervisor at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
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 a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure analyzers were stored as required by the manufacturers. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Cell Dyn Ruby analyzer; (b) Routine Urinalysis testing was performed using the Siemens Advantus analyzer. (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzers. The manufacturers required the relative humidity be maintained as follows: (a) Cell Dyn Ruby- range of 20-85%; (b) Siemens Advantus - range of 20-80% (3) The surveyor reviewed laboratory records from January 2018 through June 2018 and identified the humidity readings were less than 20% (to accommodate both analyzers) for 1 of 7 months as follows: (a) January - 11 of 31 humidity readings were less than 20% (days 2,3,4,5,13,14,15,16,17,18,19). (4) The

	surveyor reviewed the records with the technical consultant who stated the humidity of the laboratory had been maintained below 20% as indicated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the technical consultant, the laboratory failed to follow written quality control policies. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyor: (a) The laboratory performed patient PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR test cartridge and 2 iSTAT analyzers (serial numbers 353107 and 353689); (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Later during the survey, the surveyor reviewed the IQCP that had been developed for the test system. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested once a month and with each new lot or shipment of test cartridges for each analyzer; (3) The surveyor then reviewed QC (quality control) records for 15 months (July 2017 through September 2018) and identified the laboratory failed to follow the written QCP of performing quality control testing once a month for each analyzer. Quality control testing had not been performed as follows: (a) Between 06/29/18 and 08/01/18 for serial numbers 353107 and 353689. (4) The findings were reviewed with the technical consultant who stated the laboratory had not performed quality control testing for each analyzer as required by the QCP.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for 12 persons who performed moderate complexity testing during 2017 and 2018. For 1 of the 7 persons (testing person #7), there was no evidence an annual evaluation had been performed in 2018; (2) The surveyor reviewed the findings with the technical consultant. The technical consultant stated

	the annual evaluation had not been performed as indicated above in 2018 for the testing person. NOTE: D6054 was cited on the previous recertification survey performed on 06/12/17.