Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0474552	11/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab - Warren Clinic Springer	6160 South Yale Avenue, 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 11/15/18. The findings were reviewed with the general supervisor at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2017 Hematology Event (i) RDW (Red Cell Distribution Width) - 3 of 5 results exhibited a negative bias (aa) Sample AST-03- SDI of -2.2 (bb) Sample AST-04- SDI of -2.1 (cc) Sample AST-05- SDI of -2.3 (b) First 2018 Hematology Event (i) RDW - 5 of 5 results exhibited a negative bias (aa) Sample AST-01- SDI of -2.5 (bb) Sample AST-02- SDI of -2.1 (cc) Sample AST-03- SDI of -2.9 (dd) Sample AST-04- SDI of -2.9 (ee) Sample AST-05- SDI of -2.2 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the general supervisor who stated the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance

	(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to evaluate the accuracy of testing when a proficiency result had not been graded by the proficiency program. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2017 and 2018 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2017 second event (aa) Urobilinogen UA-03 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) Surveyor #2 asked the general supervisor if the results had been documented as evaluated. The general supervisor reviewed the records and stated the non-graded results had not been documented as reviewed.
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 general supervisor, the laboratory failed to follow written quality control policies. Findings include: (1) At the beginning of the survey, the general supervisor stated the following to surveyor #1: (a) The laboratory performed patient PT/INR (Prothrombin Time /International Normalized Ratio) testing using the PT/INR test cartridge and three iSTAT 1 analyzers (serial numbers 304488, 383684, and 347704); (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Later during the survey, surveyor #1 reviewed the IQCP (Individualized Quality Control Plan) 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) Surveyor #1 then reviewed QC (quality control) records for 10 months (January 2018 through October 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 03/14/18 and 06/12/18 for serial numbers 304488 and 383684; (b) Between 06/12/18 and 08/13/18 for serial numbers 304488 and 383684. (4) The findings were reviewed with the general supervisor who stated the laboratory had not performed quality control testing for each analyzer as required by the QCP.
D5775	COMPARISON OF TEST RESULTS

	CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the general supervisor, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using three different analyzers. Findings include: (1) At the beginning of the survey, the general supervisor stated to surveyor #1 BNP (B-Type Natriuretic Peptide), Troponin I, and PT/INR (Prothrombin Time /International Normalized Ratio) testing were performed using three iSTAT 1 analyzers (serial numbers 304488, 383684, and 347704); (2) Later during the survey, surveyor #1 asked the laboratory general supervisor if the relationship between the analyzers for BNP, Troponin I, and PT/INR testing had been evaluated twice annually during the review period of April 2017 through the day of the survey. The general supervisor verified the relationship between the analyzers had not been evaluated during the review period; (3) Surveyor #1 then reviewed the procedure manual and could not locate a policy/procedure describing the laboratory's method to compare the testing performed on the three iSTAT 1 analyzers. Surveyor #1 asked the general supervisor if the laboratory had a written policy/procedure describing the laboratory's method for comparing the BNP, Troponin I, and PT/INR testing performed on the analyzers, including the criteria defining acceptable differences between the testing performed on the three analyzers. The general supervisor stated a policy/procedure had not been written.