Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2089971	01/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Ba Kenosha	1801 E Kenosha St, Broken Arrow, 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 findings were reviewed with the laboratory director and technical consultant #1 at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and technical consultant #1, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) At the beginning of the survey, the laboratory director stated the laboratory used the Siemens CLINITEK Status Analyzer to perform macroscopic urinalysis testing; (2) Surveyor #2 reviewed the manufacturer's instructions for the analyzer which required a relative humidity of 18-80%; (3) Surveyor #2 reviewed the humidity records between the following: (a) January 01, 2016 through April 20, 2016 (b) December 06, 2016 through January 30, 2017 (c) December 21, 2017 through January 09, 2018 (4) Humidity - for 29 of 159 days the documented humidity was less than 18% (a) January 2016 - Days 10,11,17,18 (b) February 2016 - Days 9,10,13,14 (c) December 2016 - Days 10,15,18,19,20,21,30 (d) January 2017 - Days 5,6,7,8,9,28 (e) December 2017 - Days 27,28,31 (f) January 2018 - Days 1,2,3,4,6 (5) The surveyors reviewed the findings with the laboratory director and technical consultant #1 who stated the laboratory failed to follow manufacturer's storage instructions for Siemens CLINITEK Status Analyzer.
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 laboratory director and technical consultant #1, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following was identified: (a) 2016 Hematology - 3rd Event (i) Platelet Count - The laboratory received a score of 80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (2) The surveyors reviewed the above findings with laboratory manager and technical consultant #1 who stated the laboratory had not thoroughly reviewed and evaluated proficiency testing results.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written procedure, and interview with the laboratory director and technical consultant #1, the laboratory failed to ensure control procedures monitored the accuracy and precision of the analytic process. Findings include: (1) At the beginning of the survey, the laboratory director and technical consultant #1 stated to the surveyors: (a) CBC (Complete Blood Count) testing was performed on the Abbott Cell-Dyn Emerald analyzer; (b) Three levels (Low, Normal and High) of Abbott Cell-Dyn 18 Plus Control quality control (QC) materials were performed each day of patient testing. (2) Later during the survey, surveyor #2 reviewed the following: (a) The laboratory's written quality control procedure which stated," Follow Procedure to establish acceptable +/- 2SD ranges". Technical consultant #1 explained to the surveyors each new lot of QC materials were tested 20 times to establish a mean and 2 SD (standard deviations) range; (b) Package insert, which stated "The MEAN RANGE does not represent standard deviations (SD)". (3) The surveyors reviewed the records for 3 lot numbers of quality control materials used from 07/01/2017 to date. It was identified that, although the laboratory had established their own means and ranges for each lot number, they utilized calculated averages as their means and limits of acceptability, which had been derived from the package insert and laboratory established values. Examples were as follows: (a) Low control (lot #L7156), normal control (lot #N7156) and high control (lot #H7156) put into use 07/01/2017 through 09/22/2017. (i) RBC (red blood cell) (aa) Low control - (i) The package insert mean was 2.3, the laboratory

established a mean of 2.34, but a calculated (average) mean of 2.32 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 2.10, the laboratory established a lower limit of 2.21, but the calculated (average) lower limit of 2.15 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 2.5, the laboratory established an upper limit of 2.48, but the calculated (average) upper limit of 2.49 had been used to evaluate quality control results. (bb) Normal control (i) The package insert mean was 4.28, the laboratory established a mean of 4.36, but a calculated (average) mean of 4.32 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 4.0, the laboratory established a lower limit of 4.19, but the calculated (average) lower limit of 4.14 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 4.5, the laboratory established an upper limit of 4.54, but the calculated (average) upper limit of 4.5 had been used to evaluate quality control results. (cc) High control (i) The package insert mean was 5.28, the laboratory established a mean of 5.36, but a calculated (average) mean of 5.32 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 5.0, the laboratory established a lower limit of 5.11, but the calculated (average) lower limit of 5.04 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 5.6, the laboratory established an upper limit of 5.61, but the calculated (average) upper limit of 5.6 had been used to evaluate quality control results. (ii) Hemoglobin (aa) Low control (i) The package insert mean was 5.8, the laboratory established a mean of 5.7, but a calculated (average) mean of 5.8 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 5.3, the laboratory established a lower limit of 5.5, but the calculated (average) lower limit of 5.4 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 6.3 the laboratory established an upper limit of 6.0, but the calculated (average) upper limit of 6.1 had been used to evaluate quality control results. (bb) Normal control (i) The package insert mean was 12.0 , the laboratory established a mean of 12.1, but a calculated (average) mean of 12.0 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 11.3, the laboratory established a lower limit of 11.7, but the calculated (average) lower limit of 11.5 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 12.7, the laboratory established an upper limit of 12.5, but the calculated (average) upper limit of 12.6 had been used to evaluate quality control results. (cc) High control (i) The package insert mean was 16.3, the laboratory established a mean of 16.3, but a calculated (average) mean of 16.3 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 15.3, the laboratory established a lower limit of 15.7, but the calculated (average) lower limit of 15.5 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 17.3, the laboratory established an upper limit of 17.0, but the calculated (average) upper limit of 17.1 had been used to evaluate quality control results. (b) Low control (lot #L7240), normal control (lot #N7240) and high control (lot #H7240) put into use 09/23/2017 through 12 /15/17. (i) RBC (red blood cell) (aa) Low control (i) The package insert mean was 2.14, the laboratory established a mean of 2.15, but a calculated (average) mean of 2.14 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 1.94, the laboratory established a lower limit of 2.01, but the calculated (average) lower limit of 1.98 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 2.34, the laboratory established an upper limit of 2.28, but the calculated (average) upper limit of 2.31 had been used to evaluate quality control results. (bb) Normal control (i) The package insert mean was 4.19, the laboratory established a mean of 4.21, but a calculated

(average) mean of 4.20 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 3.94, the laboratory established a lower limit of 3.93, but the calculated (average) lower limit of 3.94 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 4.44, the laboratory established an upper limit of 4.49, but the calculated (average) upper limit of 4.46 had been used to evaluate quality control results. (cc) High control (i) The package insert mean was 5.06, the laboratory established a mean of 5.19, but a calculated (average) mean of 5.13 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 4.76, the laboratory established a lower limit of 4.93, but the calculated (average) lower limit of 4.85 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 5.36, the laboratory established an upper limit of 5.46, but the calculated (average) upper limit of 5.41 had been used to evaluate quality control results. (ii) Hemoglobin (aa) Low control (i) The package insert mean was 5.2, the laboratory established a mean of 5.1, but a calculated (average) mean of 5.1 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 4.7, the laboratory established a lower limit of 4.8, but the calculated (average) lower limit of 4.7 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 5.7 the laboratory established an upper limit of 5.4, but the calculated (average) upper limit of 5.5 had been used to evaluate quality control results. (bb) High control (i) The package insert mean was 15.2, the laboratory established a mean of 15.3, but a calculated (average) mean of 15.3 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 14.2, the laboratory established a lower limit of 14.5, but the calculated (average) lower limit of 14.3 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 16.2, the laboratory established an upper limit of 16.1, but the calculated (average) upper limit of 16.2 had been used to evaluate quality control results. (c) Low control (lot #L7324), normal control (lot #N7324) and high control (lot #H7324) put into use 12 /15/2017 through date of survey. (i) RBC (red blood cell) (aa) Low control (i) The package insert mean was 2.22, the laboratory established a mean of 2.21, but a calculated (average) mean of 2.21 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 2.02, the laboratory established a lower limit of 2.09, but the calculated (average) lower limit of 2.06 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 2.42, the laboratory established an upper limit of 2.32, but the calculated (average) upper limit of 2.37 had been used to evaluate quality control results. (bb) Normal control (i) The package insert mean was 4.15, the laboratory established a mean of 4.14, but a calculated (average) mean of 4.14 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 3.9, the laboratory established a lower limit of 4.0, but the calculated (average) lower limit of 3.95 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 4.4, the laboratory established an upper limit of 4.28, but the calculated (average) upper limit of 4.34 had been used to evaluate quality control results. (cc) High control (i) The package insert mean was 5.09, the laboratory established a mean of 5.07, but a calculated (average) mean of 5.08 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 4.79, the laboratory established a lower limit of 4.84, but the calculated (average) lower limit of 4.82 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 5.39, the laboratory established an upper limit of 5.31, but the calculated (average) upper limit of 5.35 had been used to evaluate quality control results. (ii) Hemoglobin (aa) Normal control (i) The package insert mean was 11.2, the laboratory established a mean of 11.1, but a calculated (average)

	mean of 11.1 had been used to evaluate quality control results; (ii) The package insert lower limit of acceptability was 10.5, the laboratory established a lower limit of 10.7, but the calculated (average) lower limit of 10.6 had been used to evaluate quality control results; (iii) The package insert upper limit of acceptability was 11.9, the laboratory established an upper limit of 11.5, but the calculated (average) upper limit of 11.7 had been used to evaluate quality control results. (3) The surveyors reviewed the findings with the laboratory director and technical consultant #1 who stated the laboratory did not follow the laboratory's quality control policy to ensure control procedures monitored the accuracy and precision for CBC testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and technical consultant #1, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the laboratory director and technical consultant #1 stated the following to the surveyors: (a) The laboratory performed the following testing using the iSTAT 1 analyzer: (i) Prothrombin Time/International Normalized Ratio (PT/INR) using the PT/INR cartridge (ii) Troponin I using the cTnI cartridge (iii) B-type Natriuretic Peptide (BNP) using the BNP cartridge (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as effective 01/04/16). The QA (Quality Assessment) portion of the IQCP stated, "IQCP's should be monitored and reviewed at least annually by the Laboratory Section Director or designee"; (3) Surveyor #1 then reviewed records for the testing performed on the iSTAT 1 analyzer. There was no evidence of a QA review for the IQCP between 01/04/16 and 04/04/18; (4) Surveyor #1 reviewed the records with the laboratory director and technical consultant #1 and asked if an annual QA review had been performed in 2017. The laboratory director and technical consultant #1 stated an annual QA review had not been performed during 2017.