

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2089971	(X3) Date Survey Completed 09/11/2019
Name of Provider or Supplier Saint Francis Lab-Ba Kenosha	Street Address, City, State 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 recertification survey was performed on 09/11/19. The findings were reviewed with the laboratory director/technical consultant #1 and technical consultant #2 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2, the laboratory failed to retain quality control records for at least 2 years. Findings include: (1) At the beginning of the survey, technical consultant #2 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell-Dyn Emerald; (2) Later during the survey, the surveyor reviewed quality control records between April 2019 through August 2019 with the following identified: (a) May 2019 records were not available (b) June 2019 records were not available (c) July 2019 records were not available (3) The surveyor ask technical consultant #2 if the quality control records for May 2019, June 2019, and July 2019 could be located; (4) Technical consultant #2 stated the May 2019, June 2019, and July 2019 quality control records for CBC testing could not be located. The surveyor could not determine if the quality control records for the above months had been monitored and evaluated.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p>

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 technical consultant #2, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following: (a) Third 2018 Hematology Event - The proficiency testing program did not evaluate 1 of 5 results for Platelets. In addition, the reported result did not agree with the expected result provided on the evaluation form: (i) Platelet (HEM-02) - The reported result was 86. The expected result was a range between 49-83. (2) The surveyor further reviewed the records. There was no evidence the laboratory identified the results had not been evaluated by the proficiency testing program; and there was no evidence the laboratory investigated the discrepancy between the submitted and expected results as indicated above; (3) The records were reviewed with technical consultant #2, who stated the laboratory had not investigated the discrepancy as indicated above.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of records, procedure manual, and interview with technical consultant #2, the laboratory failed to demonstrate the performance specifications for new test methods; Findings include: (1) At the beginning of the survey, technical consultant #2 stated the laboratory began using the Abbott iSTAT analyzer (serial# 400580) to perform PT/INR (Prothrombin Time/International Normalized Ratio) testing for patient testing beginning 06/25/18; (2) The surveyor reviewed the validation records for the analyzer but could not locate any records to prove the laboratory had verified the manufacturer's reportable range; (3) The surveyor asked technical consultant #2 if any additional testing had been performed to verify the reportable range prior to reporting patient results. Technical consultant #2 stated the reportable range had not been verified.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or

both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with technical consultant #2, the laboratory failed to ensure corrective actions were taken when quality control was not performed; and failed to evaluate patient test results obtained when quality control was not performed to determine if the results had been adversely affected. Findings include: (1) At the beginning of the survey, technical consultant #2 stated the following to the surveyor: (a) The laboratory performed PT/INR (Prothrombin Time /International Normalized Ratio) testing using the Abbott iSTAT1 analyzer; (b) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (c) The results for two levels of control materials must be acceptable in order to report patient results. (2) Later during the survey, the surveyor then reviewed PT/INR quality control records for testing performed from January 2018 through August 2019. For the review period, the following was identified for 1 of 20 months: (a) Quality control results could not be located for October 2018. (3) The surveyor asked technical consultant #2 if two levels of quality control for PT/INR testing had been performed. Technical consultant #2 stated PT/INR monthly quality controls were not performed in October 2018; (5) The surveyor asked technical consultant #2 if results had been evaluated to determine if they had been adversely affected. Technical consultant #2 stated there was no evidence which would support that the results had been evaluated.