

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2089971	(X3) Date Survey Completed 01/25/2024
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 01/25/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and incoming technical consultant at the conclusion of the survey.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure the performance specification data had been evaluated prior to implementing one of two new test methods introduced into the laboratory. Findings include: (1) On 01/25/2024 at 10:00 am, the laboratory director stated the laboratory began using the Beckman Coulter DxH 520 analyzer to perform CBC (Complete Blood Count) testing on 05/15/2023; (2) A review of the performance specification records for the new test system identified no evidence the data had been signed and dated as approved by the laboratory prior to putting into use for patient testing; (3) Interview with the laboratory director on 01/25/2024 at 02:30 pm confirmed there was no documentation to prove the performance specification data had been reviewed and approved by the laboratory prior to putting into use.</p>
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 and interview with the laboratory director, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for three of seven months reviewed for testing performed using the Beckman Coulter DxH 520 Hematology analyzer. Findings include: (1) On 01/25/2024 at 10:00 am, the laboratory director stated the following: (a) The laboratory began using the Beckman Coulter DxH 520 analyzer to perform CBC (Complete Blood Count) testing on 05/15/2023; (b) Three levels of QC (quality control) materials were performed each day of patient testing. (2) A review of records from June 2023 through December 2023 identified no evidence, such as Levey-Jennings graphs and cumulative statistical data, to prove that QC results had been monitored for variances (i.e., biases, shifts, trends) for three of seven months (October, November, and December 2023); (3) Interview with the laboratory director on 01/25/2024 at 03:35 pm confirmed that QC data to include Levey-Jennings graphs and cumulative statistical data had not been printed and reviewed from October through December 2023.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 perform a negative and positive control material ten of 19 days of patient SARS-CoV-2, Influenza A, Influenza B, and RSV (Respiratory Syncytial Virus) testing reviewed from October through December 2023. Findings include: (1) On 01/25/2024 at 10:10 am, the laboratory director stated the following: (a) The laboratory began performing SARS-CoV-2, Influenza A, Influenza B, and RSV testing using the Cepheid Gene Xpert DX analyzer on 10/23/2023; (b) An IQCP (Individualized Quality Control Program) had not been developed for the test system (the laboratory was in the process of developing an IQCP). (2) A review of the test volume list completed for the survey identified the laboratory performed approximately 24 of each of the tests annually; (3) A review of QC (Quality Control) and patient testing

records for testing performed from October through December 2023 identified negative and positive QC materials had not been documented as performed each day of patient testing for ten of 19 days. The specific days of patient testing were 10/27/2023; 11/14,17,20,27,30/2023; and 12/13,20,21,26/2023; (4) The records were reviewed with the laboratory director who stated on 01/25/2024 at 04:15 pm, negative and positive QC materials had not been documented as performed as stated above.