

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2089971	(X3) Date Survey Completed 10/04/2021
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 10/04/2021. The findings were reviewed with the laboratory director and technical consultant #2 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <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).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 1 of 4 Hematology events reviewed. Findings include: (1) On 10/04/2021, the surveyor reviewed proficiency testing records for the first, second, and thirds events in 2020; and the first event in 2021. The following was identified for 1 of 4 Hematology events: (a) First 2020 Event for Blood Cell ID (Educational) - 1 of 5 results had not been graded by the proficiency testing program: (i) For 1 of 5 results (ECI-01), the following was identified: (aa) ECI-01 - Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The surveyor reviewed the records with technical consultant #2 who stated on 10/04/2021 at 12:26 pm, the laboratory had not evaluated the result that was not graded by the proficiency testing program and corrective action had not been taken as indicated.</p>

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

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 perform calibration procedures as required by the manufacturer for 1 of 4 calibrations. Findings include: (1) On 10/04/2021 at 10:35 am, technical consultant #2 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell-Dyn Emerald analyzer; (2) The surveyor reviewed the manufacturer's instructions, contained in the operator's manual which were as follows: (a) Section 6 titled, "When to Calibrate" described the schedule and procedure for calibration of the Cell-Dyn Emerald analyzer and stated, "Calibration verification criteria include:" (i) "At least every six months" (3) The surveyor reviewed calibration records from December 2019 through the day of the survey (10/04/2021) and identified the following: (a) Calibration had not been performed between 08/04/2020 and 06/04/2021 (4) The surveyor reviewed the findings with technical consultant #2 who stated on 10/04/2021 at 01:48 pm, the calibration procedure had not been performed as indicated above.