

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442158	(X3) Date Survey Completed 01/23/2018
Name of Provider or Supplier Saint Francis Laboratory Sikeston	Street Address, City, State 1012 North Main Street, Sikeston, MO	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2016, 2017 calibration records for the Siemens Dimension and the Abbott Architect i1000 chemistry analyzer for the analytes of sodium, potassium, chloride, thyroid stimulating hormone(TSH), prostatic specific antigen(PSA), and ferritin and interview with the technical supervisor, the laboratory failed to perform at least a three point calibration(a minimal, mid-point, and maximum) verification every six months. Findings: 1. Review of 2016 and 2017 calibration records for the Siemens</p>

Dimension and Abbott Architect i1000 chemistry analyzer for the analytes: sodium, potassium, chloride, PSA, TSH, and ferritin revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value every six months. 2. Interview with the technical supervisor on January 23, 2018 at 1:00 PM confirmed the laboratory failed to perform at least a 3 point calibration every six months for the analytes of sodium, potassium, chloride, TSH, PSA, and ferritin for the years 2016, 2017.

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 review of quality control (QC) procedures, patient and QC logs and interview with the technical supervisor, the laboratory failed to perform a positive and negative control 7 of 48 testing days for moderately complex human chorionic gonadotropin(HCG) kit testing. Findings: 1. Review of QC procedures for the Alere HCG kit testing showed the laboratory allowed usage of serum for HCG. Review of the procedures showed "Positive and negative HCG serum controls are run each day of patient testing". 2. Review of the patient and QC documentation logs revealed the laboratory failed to perform a positive and negative external control for 7 of 48 patient testing days from August 1, 2017 to December 31, 2017. 3. Interview with the technical supervisor on January 23, 2018 at 1:00 PM confirmed, the laboratory did not test a positive and negative control each day of testing for HCG kit testing.