

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1070351	<b>(X3) Date Survey Completed</b>  07/29/2019
<b>Name of Provider or Supplier</b>  Saint Francis Physician Network, Llc	<b>Street Address, City, State</b>  2996 Kate Bond Road Suite 205, Bartlett, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 observation of the laboratory, review of the complete blood count (CBC) instrument records and interview with the technical consultant, the laboratory failed to perform calibration every six months, in 2019. The findings include: 1) Observation on July 29, 2019 at 1:20 p.m. of the laboratory revealed the Beckman Coulter AcT diff2 CBC instrument (serial number BB44317) in use for patient testing. 2) Review of the CBC instrument records revealed installation of the CBC instrument on</p>

December 4, 2018, with no calibration performance at the six month due date, June 2019. 3) Interview on July 29, 2019 at 4:00 p.m. with the technical consultant confirmed the CBC instrument calibration due date was in June 2019, which was not performed.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of patient number one final complete blood count (CBC) report, the CBC instrument printout, the quality assessment (QA) plan, interview with testing personnel number two and the technical consultant, the laboratory failed to have an effective quality assessment plan for review of patient reports containing the date of performance, in 2019. The findings include: 1) Review of patient number one final CBC report revealed no date of performance on the electronic medical record (EMR) "In-House CBC w/Auto Diff" form. The "CBC w/auto diff flowsheet" for patient number one stated the date of performance as 07-02-19. 2) Review of the CBC instrument printout for patient number one revealed the date of performance as 06-27-19. 3) Review of the QA plan revealed the patient test management does not include a review for date of performance and date of reporting. 4) Interview on July 29, 2019 at 3:45 p.m. with testing personnel number two confirmed patient number one CBC sample was collected on June 27, 2019, performed on June 27, 2019 and recorded on the EMR CBC records as performed on July 2, 2019 during the patient office visit. The patient CBC results are manually typed into the patient EMR and the CBC instrument printout is not scanned into the patient EMR. 5) Interview on July 29, 2019 at 4:00 p.m. with the technical consultant confirmed the date of performance for CBC testing is not reviewed with the patient test management review. The quality assessment plan does not include to review for date of performance and date of reporting.

**D6072**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of the complete blood count (CBC) quality control (QC) records and interview with testing personnel number one, the testing personnel failed to follow the CBC QC policies when the CBC QC lot number changes, in 2019. The findings include: 1) Review of the CBC QC records revealed that from July 2, 2019 to July 24, 2019 the correct lot numbers, expiration dates, and acceptable limits were not entered into the CBC instrument with the new QC lot number change. The daily CBC QC instrument printouts were reviewed daily by testing personnel numbers one and two with no reorganization of incorrect lot numbers, expired dates and incorrect limits. 2) Interview on July 29, 2019 at 4:10 p.m. with testing personnel number one confirmed

that on July 2, 2019 to July 24, 2019, the CBC QC lot number samples were changed but the correct lot numbers, expiration dates and acceptable limits were not entered into the CBC instrument. The daily CBC QC instrument printouts were reviewed daily by testing personnel numbers one or two, but didn't clearly understand that the CBC QC lot numbers, expiration dates and acceptable limits needed to be updated with each shipment of new lot numbers.