

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0722040	(X3) Date Survey Completed 04/03/2023
Name of Provider or Supplier Saint Francis Laboratory Poplar Bluff	Street Address, City, State 225 Physicians' Park Drive Suite 104, Poplar Bluff, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of chemistry proficiency testing (PT) results reported to the CLIA database by the PT provider for 2022/2023 and interview with the technical consultant (TC) on March 27, 2023 at 1:00 PM , the laboratory failed to successfully participate in PT. Refer to D-tag 2096, unsatisfactory performance in two consecutive urea nitrogen (BUN) PT challenges.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of chemistry proficiency testing (PT) results reported to the CLIA database by the PT provider for 2022/2023 and interview with the technical consultant (TC), the laboratory failed to achieve satisfactory performance for urea nitrogen (BUN) in two consecutive testing events. Findings: 1. Review of the chemistry- core PT results for the third event of 2022 showed the laboratory obtained an unsatisfactory score of 20 percent for the analyte BUN. 2. Review of the chemistry- core PT results for the first event of 2023 showed the laboratory obtained an unsatisfactory score of 40 percent for the analyte BUN. 3. Interview with the technical consultant (TC) on March 27, 2023 at 1:00 PM confirmed the laboratory failed to achieve satisfactory performance for BUN in two consecutive testing events.