

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1063281	(X3) Date Survey Completed 06/07/2019
Name of Provider or Supplier Family Medicine Of Saye Brook Llc	Street Address, City, State 106 Lansford Court, Myrtle Beach, SC	
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 record review and technical supervisor interview, the laboratory failed to successfully participate in proficiency testing for the specialty of chemistry, the analyte creatinine, for two of three consecutive proficiency events reviewed (2018, quarters 1 and 3, and the analyte total protein, for two consecutive events reviewed (2018, quarters 1 and 2). See D2096</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 proficiency testing record review and technical supervisor interview, the laboratory failed to achieve satisfactory performance for creatinine for two out of three consecutive testing events (2018, quarters 1 and 3) and total protein for two consecutive testing events (2018, quarters 1 and 2). Findings include: 1. Review of graded reports from American Academy of Bioanalysts (AAB) revealed the following scores: a. 2018, Quarter 1 Creatinine: 60% b. 2018, Quarter 3 Creatinine: 60% c. 2018, Quarter 1 Total Protein: 40% d. 2018, Quarter 2 Total Protein: 60% 2. The failures were confirmed by technical supervisor during the exit interview at 11:45 am.