

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0983317	(X3) Date Survey Completed 11/16/2018
Name of Provider or Supplier Lake Martin Vascular Clinic	Street Address, City, State 815 Lee Street, Alexander City, AL	
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 a review of the CMS Casper reports (#153/#155) and a review of proficiency testing evaluations from American Association of Bioanalysts (AAB), the surveyor determined the laboratory failed to successfully participate in proficiency testing for Chemistry Events #1 and #3 for Na (Sodium), two of three consecutive testing events. These failures resulted in an initial unsuccessful proficiency testing for the laboratory. The findings include: 1. The Casper reports #153 and #155 revealed the laboratory failed Na testing for Event #1, 2018 (scored 60 %) and Event #3, 2018</p>

(scored 60 %), two of three consecutive testing events. 2. A review of the AAB proficiency testing evaluations for Event #1 and #3 of 2018 revealed the above mentioned scores for Na.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

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 a review of the CMS Casper reports (#153/#155) and a review of proficiency testing evaluations from American Association of Bioanalysts (AAB), the surveyor determined the laboratory failed to satisfactorily perform in proficiency testing for Chemistry Events #1 and #3 for Na (Sodium), two of three consecutive testing events. These failures resulted in an initial unsuccessful proficiency testing for the laboratory. The findings include: 1. Refer to D2016 (493.803, Successful Participation). Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor