

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0326738	(X3) Date Survey Completed 03/02/2018
Name of Provider or Supplier Lake Cumberland Medical Associates-Hardin Lane	Street Address, City, State 110 Hardin Lane, Suite 9, Somerset, KY	
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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on desk review of Hematology proficiency testing results from the American Proficiency Institute on 03/02/2018, the laboratory failed to successfully participate in the White Blood Cell Differential in two (2) consecutive testing events. See D2121 and D2130
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte

in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on desk review of Hematology proficiency testing results from the American Proficiency Institute on 03/02/2018, the laboratory failed to attain a satisfactory score of at least eighty percent (80%) on the White Blood Cell Differential. The findings include: The laboratory scored an unsatisfactory zero percent (0%) in the second testing event of 2017 and scored an unsatisfactory fifty-three (53%) in the third testing event of 2017.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

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

This STANDARD is not met as evidenced by:

Based on desk review of Hematology proficiency test results from the American Proficiency Institute on 03/02/2018, the laboratory failed to successfully achieve satisfactory performance for White Blood Cell Differential in two (2) consecutive testing events. The findings include: The facility scored zero percent (0%) in the second testing event of 2017 and scored fifty-three percent (53%) in the third testing event of 2017 for an unsuccessful performance.