Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0326738	(X3) Date Survey Completed 05/24/2018
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 05/24/2018, the laboratory failed to successfully participate in the White Blood Cell (WBC) Differential certified analyte in three consecutive testing events. This is the second unsuccessful proficiency failure. See the first unsuccessful failure dated 03/02/2018. 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 05/24/2018, the laboratory failed to attain a satisfactory score of at least 80 percent on the White Blood Cell Differential certified analyte. Findings include: The laboratory scored an unsatisfactory 0 percent in the second testing event of 2017, scored an unsatisfactory 53 percent in the third testing event of 2017, and scored an unsatisfactory 67 percent in the first testing event of 2018.
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 testing results from the American Proficiency Institute on 05/24/2018, the laboratory failed to successfully achieve satisfactory performance for the White Blood Cell Differential certified analyte in three consecutive testing events. Findings include: The facility scored 0 percent in the second testing event of 2017, scored 53 percent in the third testing event of 2017, for a first unsuccessful performance and scored 67 percent in the first testing event of 2018 for a second unsuccessful performance.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of Hematology proficiency testing results from the American Proficiency Institute on 05/24/2018, the laboratory director failed to fulfill the responsibility of evaluating the laboratory's performance of the failed White Blood Cell Differential certified analyte. Findings include: The corrective action taken for the first unsuccessful proficiency failure dated 03/02/2018, failed to correct the White Blood Cell Differential which is evidenced by the second unsuccessful proficiency failure occurring in the first testing event of 2018.