

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1031507	(X3) Date Survey Completed 12/07/2018
Name of Provider or Supplier Mid America Clinical Laboratories	Street Address, City, State 8550 Naab Rd Ste 205, Indianapolis, IN	
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 document review and interview, the laboratory failed to achieve a passing score of 80% for Cell Identification or WBC (white blood cell) Differential for two consecutive events in 2018 (Events 2&3). Refer to D-2130.
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 document review and interview, the laboratory failed to achieve a passing score of 80% for Cell Identification or WBC (white blood cell) Differential for two consecutive events in 2018 (Events 2&3). Findings Include: 1) Review of CMS-155 report indicated the following failing scores for Cell Identification or WBC Differential: a) Event 2/2018=24% b) Event 3/2018=8% 2) In interview on 12/07/18 at 1:22 pm, SP-1 confirmed the above failing scores for Cell Identification or WBC Differential.