

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0354909	(X3) Date Survey Completed 04/19/2018
Name of Provider or Supplier Mid America Clinical Laboratories	Street Address, City, State 8301 Harcourt Rd Ste 200, 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 record review and interview, the laboratory failed to successfully participate in proficiency testing (PT) for 2 out of 3 events (2/2017 and 1/2018) in the specialty of Routine Chemistry for the analyte, Albumin, Refer to D-2096.
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 record review and interview, the laboratory failed to successfully participate in proficiency testing (PT) for 2 out of 3 events (2/2017 and 1/2018) in the specialty of Routine Chemistry for the analyte, Albumin. Findings include: 1) Review of Oscar Report 155D (Individual Laboratory Profile) indicated the following unsatisfactory scores for Albumin: Event 2 (2017)=40% and Event 1 (2018)=40%. 2) Review of proficiency testing scores received from MLE (Medical Laboratory Evaluation), confirmed the above Albumin scores. Staff member SP-2 (MLE representative) sent an email on 4/18/18 at 4:24 pm confirming unsatisfactory scores. 3) In interview on 4/18/18 at 2:14 pm, SP-1 (Facility) confirmed the above failing scores of 40% for Event 2/2017 and 40% for Event 1/2018 for the analyte, Albumin.