Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D1031507	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mid America Clinical Laboratories	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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: A) Based on record review and interview, the laboratory failed to retain quality control records for 9 of 11 patients (PT) 1-8 and PT-11 reviewed for January 2017 to April in 2018 for Hematology testing (CBC-Complete Blood Count). Findings Include: 1) Policy titled, "Quality Control Out-of-Range Procedure," dated 5/7/18, and signed by the laboratory director indicated the following, "...QUALITY CONTROLS The specified controls are run each day that testing is performed..." 2) Medical record review indicated the following patients had CBC testing performed in 2017 and January to April of 2018; Patients (PT) 1-8 and PT-11, without quality control records being retained: PT-1=9/14/17 PT-2=10/24/17 PT-3=11/7/17 PT-4=12/13/17 PT-5=1/1/718 PT-6=2/13/18 PT-7=3/14/18 PT-8=4/24/18 PT-11=5/24/17 3) In interview on 7/24/18 at 1:40 pm, SP-1 (staff person #1) confirmed quality control records had not been maintained for January 2017 to April in 2018. B) Based on record review and interview, the laboratory failed to document and retain maintenance records for one of one Hematology analyzer reviewed for January 2017 to April in 2018 for CBC-Complete Blood Count testing. Findings Include: 1) Policy titled, "HEMATOLOGY COMPLETE BLOOD COUNT (CBC)," dated 6/29/18, and signed by the laboratory director indicated the following, "...MAINTENANCE 1. Daily...e. Record on Maintenance Log..." 2) Medical record review indicated the following patients had CBC testing performed in 2017 and January to April of 2018; Patients (PT) 1-8 and PT-11, without maintenance procedures being documented and retained: PT-1=9/14/17 PT-2=10/24/17 PT-3=11/7/17 PT-4=12/13/17 PT-5=1/1/718 PT-6=2/13/18 PT-7=3/14/18 PT-8=4/24/18 PT-11=5/24/17 3) In interview on 7/24/18 at 1:42 pm, SP-1

	(staff person #1) confirmed maintenance records had not been documented and retained for January 2017 and to April in 2018.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy(s) of the attestation statement, instrument printouts, and director review for one of three proficiency testing events reviewed (Event 2/2017) for Hematology testing (CBC-Complete Blood Count). Findings Include: 1) Review of Event 2/2017 proficiency testing documentation, indicated none was available for the attestation statement, instrument printouts, and director review. 2) Medical record review indicated Patient #11 (PT-11) had CBC testing performed during Event 2/2017 on 5/24/17. 3) In interview on 7/24/18 at 2:33pm, SP-1 (staff person #1) confirmed the laboratory failed to maintain a copy(s) of the attestation statement, instrument printouts, and director review for Event 2/2017.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain documents for a QA (Quality Assurance) Program for one of one specialty reviewed, Hematology, in 2017. Findings Include: 1) Review of the Quality Assurance (QA) program for general laboratory systems indicated none was available for the year, 2017. 2) In interview on 7/24/18 at 3:02 pm, SP-1 (staff person #1) confirmed there was no QA program for the year, 2017.