

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0680840	<b>(X3) Date Survey Completed</b>  01/07/2019
<b>Name of Provider or Supplier</b>  Mid America Clinical Laboratories	<b>Street Address, City, State</b>  395 Westfield Rd Ste #2981, Noblesville, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain proficiency testing documentation for one of two years reviewed (2017) in the specialty, Hematology (CBC=Complete Blood Count). Annual testing for Hematology=1,757. Findings Include: 1) Review of proficiency testing documentation for 2017 indicated none was available for review. 2) Medical record review indicated patients (PT) #1-#9 had CBC testing performed in 2017: PT#1=2/27/17 PT#2=2/27/17 PT#3=5/2/17 PT#4=5/2/17 PT#5=7/10/17 PT#6=7/10/17 PT#7=7/17/17 PT#8=11/15/17 PT#9=11/15/17 3) In interview on 1/7/19 at 11:11 am, SP-2 (staff person #2) confirmed the laboratory failed to maintain proficiency testing documentation for 2017 in the specialty of Hematology (CBC testing).</p>
<b>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation, document review, and interview the laboratory failed to document maintenance activities for one of one analyzer reviewed (Sysmex XS 1000i, Serial Number=74522) for 2017 and 2018. Annual testing for Hematology=1,757. Findings Include: 1) On 1/7/19 at 2:29 pm, a tour of the lab was conducted with SP-1 and SP-2. One analyzer was observed in the laboratory testing area for CBC (Complete Blood Count) testing, a Sysmex XS 1000i (Serial Number=74522). 2) Review of maintenance documentation for the Sysmex XS 1000i indicated none was available for the following months: Feb 2017 through Feb 2018. 3) Medical record review indicated patients (PT) #1-#11 had CBC testing performed on the Sysmex XS 1000i in 2017 and 2018: PT#1=2/27/17 PT#2=2/27/17 PT#3=5/2/17 PT#4=5/2/17 PT#5=7/10/17 PT#6=7/10/17 PT#7=7/17/17 PT#8=11/15/17 PT#9=11/15/17 PT#10=2/16/18 PT#11=2/16/18 4) In interview on 1/7/19 at 2:08 pm, SP-2 confirmed there was no maintenance documentation available to review from Feb 2017 through Feb 2018 for the Sysmex XS 1000i analyzer.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:  
Based on document review and interview, the laboratory failed to provide the staff member performing the test for 11 of 17 test reports reviewed. Annual testing for Hematology=1,757. Findings Include: 1) Review of patient test reports (PTs #1-#11, PT=patient) indicated the identity of the laboratory testing personnel was not available. 2) In interview on 1/7/19 at 2:46 pm, SP-2 confirmed the identity of the testing personnel for PTs #1-#11 was not available for review.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on document review and interview, the laboratory director failed to ensure one of two testing personnel (SP-3) received the appropriate training for moderately complex testing (CBC=Complete Blood Count). Annual testing for Hematology=1,757. Findings Include: 1) Review of CMS-209 [Laboratory Personnel Report (CLIA)] indicates SP-3 (SP=staff person) is a testing person. 2) Review of training

documentation for SP-3 indicated none was available. 3) Medical record review indicated SP-3 performed laboratory testing on the Sysmex XS 1000i and reported CBC results for PT#17 (PT=patient) on 11/14/18. 4) In interview on 1/7/19 at 2:42 pm, SP-2 confirmed SP-3 had a hire date of 11/5/18 and there was no Sysmex XS 1000i training documentation available for review.