

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1068886	(X3) Date Survey Completed 08/17/2018
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 12210 West 87th Street, Lenexa, KS	
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
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: D6018 Based on review of 2017 proficiency testing(PT) and interview with laboratory staff, the director failed to ensure all PT reports are evaluated and failed to identify any problems that require corrective action. Findings: 1. Review of the 2017 second event for infectious mononucleosis proficiency testing showed a result of 80 percent with no documented corrective action 2. Review of the 2017 third event for infectious mononucleosis proficiency testing showed a result of 60 percent with no documented corrective action. 3. Interview with laboratory staff on August 17, 2018 at 12:00 PM confirmed the laboratory director failed to ensure all PT reports are evaluated to identify any problems that require corrective action.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>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)(13) Ensure that an approved procedure manual is available to all</p>

personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

D6031 Based on review of the procedure manual revealed and interview with the laboratory staff on August 17, 2018 confirmed, the laboratory director failed to have an approved manual available to laboratory personnel.