

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D1063766	(X3) Date Survey Completed 09/19/2019
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 4750 Main St, Bridgeport, CT	
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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to establish written policies and procedures to assess consultant competency for their regulatory roles and responsibilities for accurate and reliable testing and reporting. Findings include: 1. Record review of employee competency records on 9/19/19 revealed the laboratory did not have a policy or procedure to assess technical and clinical consultants for their regulatory roles and responsibilities and they were not assessed. 2. Staff interview with the laboratory director on 9/19/19 at 11:20 AM confirmed the above findings.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to evaluate and document performance for moderate complexity testing personnel (TP) in the specialty of hematology. Findings include: 1. Record review of 2017 and 2018 employee competency records on 9/19/19 revealed the laboratory failed to evaluate and document competency assessment for 1 of 1 TP in 2018. 2. Staff interview with the laboratory director (LD) on 9/19/19 at 12:05 PM confirmed the above finding. The LD stated the TP evaluation was started but not completed. 3. The laboratory performs 47 tests annually in the specialty of hematology.