

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2136523	(X3) Date Survey Completed 07/20/2023
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 270 Smith Church Road, Roanoke Rapids, NC	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2021, 2022 and 2023 American Proficiency Institute (API) hematology and chemistry proficiency testing (PT) records and interview with technical consultant (TC) 7/20/23, the laboratory failed to ensure all testing personnel (TP) participated in PT. Findings: Review of laboratory policy "Proficiency Testing Policy" revealed "12. Integrate proficiency testing samples within the routine laboratory workload and analyze the samples using personnel who routinely test patient samples...". Review of 2021, 2022 and 2023 API PT records revealed TP #1 did not participate in the hematology and chemistry PT events for 2021, 2022 and 2023. Interview with TC at approximately 11:00 a.m. confirmed TP #1 had not participated in the 2021, 2022 and 2023 hematology and chemistry PT events. She stated TP #1 was a float and covering multiple facilities so it was difficult to ensure she was participating in the PT events at this facility.</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> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory policy, review of 2021, 2022 and 2023 TP competency records, and interview with TC 7/20/23, the TC failed to perform an annual competency on 1 of 3 TP. Findings: Review of laboratory policy "Training and Competency Assessment Policy" revealed "C. Competency Schedule...1. Competency for nonwaived test is assessed at the following times: a. after training b. semi-annually during the first year c. Annually after the first year...". Review of 2021, 2022 and 2023 TP competency records revealed TP #1 had an initial competency assessment in March of 2021, a semi-annual competency assessment in September of 2021 and an annual competency assessment in April of 2022. There was no documentation of a competency assessment for TP #1 since April of 2022, a period of approximately 15 months in which competency was not assessed. Interview with TC at approximately 11:00 a.m. confirmed the last competency assessment for TP #1 was in April of 2022. She stated she and TP #1 were working at multiple facilities to cover the staffing shortages and she had not been available to access her competency since April of 2022.