

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0999063	(X3) Date Survey Completed 03/30/2022
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 11555 University Blvd, Sugar Land, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
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 the review of the laboratory's policy, API proficiency records from 2021-January 2022, Laboratory personnel CMS 209 report, and confirmed in an interview found the laboratory failed to test the proficiency samples by personnel who routinely perform the testing in the laboratory for four of four chemistry testing events. The findings were: 1. Review of the laboratory's policy titled Proficiency Testing Procedure (KGN-P[1].039.008b) revealed under Analyzing Proficiency Testing Material, "...4.d. Personnel who routinely perform the testing in the laboratory will test PT samples using the laboratory's routine testing methods. 4.e. Rotate PT samples over time and/or "Float" staff whenever practical...." 2. Review of API proficiency records from 2021-January 2022 revealed four of four chemistry testing events were tested by the same TP#16. 2021 Chemistry Core 1st event 2021 Chemistry Core 2nd event 2021 Chemistry Core 3rd event 2022 Chemistry Core 1st event 3. Review of Laboratory Personnel CMS 209 Report signed by the LD on 3/29/2022 revealed the laboratory has 16 TP. 4. An interview with the LD and quality manager on 3/30/22 at 10:25 am in the conference room confirmed the above findings. Key: API=American Proficiency Institute CMS=Center of Medicare and Medicaid Services LD=Laboratory Director TP=Testing personnel</p>