

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2132308	<b>(X3) Date Survey Completed</b>  06/30/2022
<b>Name of Provider or Supplier</b>  Laboratory Corporation Of America	<b>Street Address, City, State</b>  1111 Delafield St Ste 301, Waukesha, WI	
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>D6070</b>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b> CFR(s): 493.1425(b)(1)</p> <p>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with a technical consultant, testing personnel did not follow the laboratory's requirement to use a mechanical rotator when performing the Remel MONO-LEX test for thirty-five of thirty-five tests for infectious mononucleosis performed annually. Findings include: 1. Review of the laboratory procedure, "Infectious Mononucleosis Tests Qualitative and Quantitative" showed the laboratory performed infectious mononucleosis testing using the MONO-LEX latex agglutination procedure. The "Supplies, Instrumentation" section showed a clinical rotator capable of 100 rpm (rotations per minute) was needed. The procedure also included the following statement in the "Procedure" section, "Hand rotation will be used only when the clinical rotator is not working." 2. Interview with the technical consultant (staff A) on June 22, 2022 at 3:35 PM revealed the laboratory does not have a clinical rotator and has performed all MONO-LEX tests using hand rotation. The interview confirmed testing personnel have not followed the laboratory's procedures for test analysis using the MONO-LEX test kit. Email communication with staff A on June 30, 2022 at 8:19 AM confirmed the laboratory performed thirty-five mononucleosis tests annually.</p>