

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D1086722	<b>(X3) Date Survey Completed</b>  06/18/2024
<b>Name of Provider or Supplier</b>  Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b>  16970 S Kimble St, Olathe, KS	
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>D5393</b>	<p><b>PREANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1249(b)(c)</p> <p>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation of preanalytical quality assessment processes and interview with the laboratory director (LD), the laboratory failed to document preanalytical quality assessment. Findings: 1. The surveyor asked for documentation of preanalytical quality assessment for histopathology testing. Documentation provided was last made on 9/20/22. 2. The LD provided a verbal description of the process performed but was unable to provide documentation of the process since 9/20/22. Interview with the LD on 6/1824 at 9:25 a.m. confirmed, the laboratory failed to document preanalytical quality assessment. 3. This laboratory reports approximately 5090 histopathology patient reports annually.</p>
<b>D5609</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation of control procedures performed, review of</p>

patient reports, and interview with the LD, the laboratory failed to document quality control (QC) results for histopathology staining for patient reports from 9/20/22 to 6/18/24. Findings: 1. Surveyor requested QC stain documentation for Hematoxylin & Eosin (H&E) used for patient testing. No documentation was provided at the time of survey. 2. Surveyor asked if H&E stain quality was documented on the patient test report. The LD stated documentation of acceptable H&E stain quality was not included on the patient test report. 3. Interview with the LD on 6/18/24 at 9:25 a.m. confirmed, the laboratory failed to document quality control (QC) results for histopathology staining for patient reports from 9/20/22 to 6/18/24.