

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 01D2271634	<b>(X3) Date Survey Completed</b> 07/23/2025
<b>Name of Provider or Supplier</b> Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b> 171 Carraway Drive, Winfield, AL	
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>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2023-2025 Sysmex XS-1000IC analyzer calibration records, the Hematology Policy and Procedure Manual (P&amp;P), and an interview with the Manager, the laboratory failed to perform calibration on the Hematology analyzer at least every six months as per the laboratory procedure. The surveyor noted no documentation two of two Hematology analyzer calibrations due in 2023. The findings include: 1. A review of the Sysmex XS-1000IC Hematology analyzer records revealed no documentation of calibrations performed in 2023. 2. A review of the P&amp;P for Sysmex Managed Calibration, "HEM 25760 Calibration Verification (C-V) Criteria", the following calibration requirement, "...5. At least every six months". 3. The Manager confirmed the above findings during the exit conference on 07-23-2025 at 1:21 PM.</p>
<b>D6053</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p>

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with the Manager, the Technical Consultant (TC) failed to assess and document semi-annual competency for Testing Personnel 2 (TP2) and Testing Personnel 3 (TP3) within the first year of patient testing, two of the three Testing Personnel listed on Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed the TC failed to perform and document assessment of the semi-annual competency for TP2 and TP3 during the first year of patient testing, as follows: A) TP2 had initial training performed on 01-30-2023 and on 07-18-2024, however the semi-annual assessment was not completed until 04-10-2025. B) TP3 had initial training performed on 01-18-2024 and on 01-22-2025, however the semi-annual assessment was not completed until 07-17-2025. 2. The Manager confirmed the above findings during the exit conference on 07-23-2025 at 1:12 PM.