

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0690507	(X3) Date Survey Completed 11/16/2022
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 1924 Alcoa Hwy Box U-108, Knoxville, TN	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Revisit 11/15/22 to 11/16/22 Based on review of the quality control (QC) records for the Sysmex XS1000i complete blood count (CBC) instrument and interview with the laboratory manager, the laboratory failed to retain quality control ranges for the Sysmex XS1000i CBC instrument for a period of two years. The findings include: 1. Review of the laboratory's QC records for the Sysmex XS1000i CBC instrument revealed no retention of records that included the laboratory's quality control ranges prior to 01/27/22. 2. Interview with the laboratory manager on 11/16/22 at 2 pm confirmed the laboratory failed to retain documentation of the quality control ranges that were being used for the Sysmex XS1000i prior to 01/27/22.</p>