

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2040019	(X3) Date Survey Completed 09/05/2024
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 214 East Elm Street, Graham, NC	
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
D6074	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5)</p> <p>Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2023 and 2024 urinalysis quality control records, and interview with the TC (technical consultant) 9/5/24, testing personnel failed to recognize that a problem existed when incorrect quality control ranges were documented for urine microscopic controls on 186 days of testing from 11/1/23 - 8/16/24, and unacceptable results were obtained on 5 of the 186 days. Findings: Review of the product insert for the BIO-RAD qUAntify Plus Control Levels 1 and 2 revealed "... ASSIGNMENT OF VALUES The results printed in this insert were derived from replicate analyses and are specific for this lot of product. ..." Review of the laboratory's 2023 and 2024 "URINALYSIS DAILY QUALITY CONTROL LOG" revealed the laboratory had used BIO-RAD qUAntify Plus Control Level 2, lot #80802 from 11/1/23 - 8/16/24. 1. The quality control product insert listed the acceptable range for microscopic WBC (white blood cell) count on the Level 2 control as 10-50 cells per hpf (high power field), but the "URINALYSIS DAILY QUALITY CONTROL LOG" listed the acceptable range as 0-60 cells per hpf. Unacceptable WBC results were documented 2/22/24, 2/23/24, 6/3/24, 6/4/24, and 6/5/24 for the Level 2 control. 2. The quality control product insert listed the acceptable range for microscopic RBC (red blood cell) count on the Level 2 control as 10-60 cells per hpf (high power field), but the "URINALYSIS DAILY QUALITY CONTROL LOG" listed the acceptable range as 0-40 cells per hpf. Unacceptable RBC control results were documented 2/22/24 and 2/23/24 for the Level 2 control. During interview at approximately 2:30 p.m., the TC stated the laboratory must have</p>

continued to use the ranges from the previous lot number of control material instead of updating the ranges when they started using the new lot number.