

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2227560	(X3) Date Survey Completed 03/01/2022
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 17050 W 96th St, Lenexa, KS	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs, stated temperature ranges, temperature entries, lack of corrective action documentation and interview with the laboratory director (LD), the laboratory failed to document corrective action when temperatures were out of set ranges at time of survey. Findings: 1. Review of the "Daily Maintenance Log" documentation showed the laboratory failed to document any corrective action for the months of November 2022 and December 2022 for the following number of days per month for the "Lab Main Refrigerator" established temperature range 2 to 10 degrees Celsius with a documented min/max established range of 2 to 10 degrees Celsius and the "Laboratory Freezer" established temperature range -10 to -20 degrees Celsius with documented min/max established temperature range -10 to -20 degrees Celsius for two of two thermometers. a. November 2022- Seven days of temperature readings recorded were outside of acceptable range for the Lab Main Refrigerator in the Daily Maintenance Log in the "Actual" and "Min/Max" columns with no corrective actions. b. November 2022- Fourteen days of temperature recorded were outside of acceptable range for the Laboratory Freezer in the Daily Maintenance Log in the "Min/Max" columns with no corrective actions. c. December</p>

2022- Twelve days of temperature readings recorded were outside of acceptable range for the Lab Main Refrigerator in the Daily Maintenance Log in the "Actual" and "Min/Max" columns with no corrective actions. d. December 2022- Fourteen days of temperature recorded were outside of acceptable range for the Laboratory Freezer in the Daily Maintenance Log in the "Min/Max" columns with no corrective actions. 2. Interview with the LD on 3/1/22 at 9:57 am confirmed, the laboratory failed to document corrective action when temperatures were out of set ranges at time of survey.