

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D2093492	<b>(X3) Date Survey Completed</b> 02/11/2022
<b>Name of Provider or Supplier</b> Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b> 201 North Breazeale Avenue, Mount Olive, NC	
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>D5785</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of Sysmex pocH-100i operator's manual, laboratory procedure manual and 2021 and 2022 humidity logs 2/11/22, the laboratory failed to document and perform corrective action for humidity readings outside the acceptable range approximately 13 of 73 days reviewed from November of 2021 through February of 2022. Findings: Review of operator's manual for the Sysmex pocH-100i revealed under section 12.1 "Performance characteristic - Specifications...Relative humidity... 30-85%...". Review of laboratory procedure "Humidity Monitoring Policy" revealed "5. If the humidity reading is out of range: a. Supervisor or designee is informed, and patient results are held as appropriate...e. The new humidity reading on the corrective action log is recorded after the issue has been resolved.". Review of the laboratory's humidity log revealed, "2. If humidity reading is out of acceptable range: (a) Notify supervisor or designee; and (b) Record corrective action taken, date action taken, and initials on corrective action log.". Review of the laboratory's 2021 and 2022 humidity logs revealed humidity recordings below 30% for the following dates with no corrective action documented. a. 2 of 22 days in November 2021 -11/29 and 11/30. b. 2 of 21 days in December 2021- 12/1 and 12/23. c. 7 of 21 days in January 2022- 1/18, 1/19, 1/24, 1/25, 1/27, 1/28, and 1/31. d. 2 of 9 days in February 2022- 2/1 and 2/9.</p>
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p>

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of personnel records 2/11/22 and the deficiency cited at D6065, the laboratory failed to verify that 1 of 6 testing personnel (TP # 2) met the minimum education requirements for performing moderate complexity testing. Findings: See D6065.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the technical consultant (TC) 2/11/22, the laboratory failed to verify that 1 of 6 testing personnel (TP # 2) met the minimum education requirements for performing moderate complexity testing. Findings: Review of personnel records 2/11/22 revealed that TP #2 has a job description that includes performing moderate complexity testing but there was no education documentation found to meet the minimum education requirements. During interview with TC at 11:45 a.m on 2/11/22., TC confirmed TP #2 did perform moderate complexity testing.