

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2148820	(X3) Date Survey Completed 03/18/2020
Name of Provider or Supplier Labcorp Of America Holdings - Rocky Mount	Street Address, City, State 200 Nash Medical Arts Mall, Rocky Mount, 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (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 (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (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 review of 2018, 2019, and 2020 hematology records and interview with TC (technical consultant) #1 on 3/18/20, the laboratory failed to perform and document calibration of the Sysmex XS-1000iC hematology analyzer at least once every six months. Review of hematology records revealed the Sysmex was calibrated at installation on 12/12/18, but was not calibrated again until 13 months later on 1/13/20. During interview at approximately 12:00 p.m., TC #1 stated the instrument was supposed to be calibrated in June 2019. She stated testing personnel said that the instrument was not calibrated because Sysmex service never came to do it.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with TC (technical consultant) #1 on 3/18/20, the TC failed to perform and document a semiannual competency evaluation for 1 of 2 testing personnel (TP #2) during the first year of patient testing. Review of personnel records revealed TP #2 was trained in February 2019. There was no documentation of a competency evaluation for TP #2 since the training. During interview at approximately 11:05 a.m., TC #1 confirmed that the semiannual competency evaluation was not performed. She stated the annual competency for TP #2 is due now.

D6073

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(4)

Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, review of 2018, 2019, and 2020 temperature and humidity logs, and review of corrective action logs 3/18/20, testing personnel failed to follow the laboratory's corrective action policy for humidity readings outside the acceptable limits. The laboratory's "Humidity Monitoring Policy" states "... 7. If the humidity reading is out of range: a. Inform the supervisor or designee and hold patient results as appropriate. b. The supervisor or designee will assess the condition of reagents and/or instrument performance to determine whether either have been compromised and take necessary action. c. Document any significant change in instrument or method performance as indicated by calibration and/or quality control values. d. If necessary, perform testing using an unaffected alternate method or send specimens to another ... facility for testing. e. Record the new humidity reading on the corrective action log after the issue has been resolved. ..." Review of 2018, 2019, and 2020 temperature and humidity logs revealed humidity readings outside the acceptable limits of 30-85% on 31 of 81 days from 11/1/18 to 2/28/19. Review of corrective action logs revealed corrective action was documented on only 5 of the 31 days with out-of-range humidity readings.