

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0966040	(X3) Date Survey Completed 01/12/2022
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 1410 Mcfarland Blvd Suite Lca, Tuscaloosa, AL	
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
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with the Laboratory Supervisor, the surveyor determined the laboratory failed to submit proficiency testing results by the submission deadlines for Hematology testing for Event #3 2020. The laboratory scored zero percent (0%) for this event, due to the failure to timely submit the results. This affected one of eight PT events reviewed by the surveyor. The findings include: 1. A review of the PT records revealed the due date to submit API proficiency testing results for the 3rd Event 2020 was 11/24/2020. The API Performance Evaluation for 3rd Event 2020 revealed zero percent (0%) for Hematology Complete Blood Count (CBC) failure to participate. 2. During an interview on 01/12/2022 at 2:40 PM, the Laboratory Supervisor confirmed the 3rd Event 2020 was not performed due to missing the submission date and patient testing was still being performed during this time period.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.</p>

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of temperature records and an interview with the Laboratory Supervisor, the laboratory failed to document room temperature, humidity, and refrigerator temperatures. This was noted for almost 4 months for room temperature and humidity (required for the hematology analyzer) and for one year for the refrigerator temperatures (required for the hematology controls) reviewed by the surveyor. The findings include: 1. A review of the temperature records revealed the following: a) From 10/23/2020 to 02/12/2021, room temperature and humidity were not documented. b) From March 2020 to 02/12/2021, the refrigerator temperatures were not documented. 2. During an interview on 01/12/2022 at 1:40 PM, the Laboratory Supervisor confirmed the documents could not be located for the dates listed above.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

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.

This STANDARD is not met as evidenced by:

Based on a review of the AcT Diff 2 Hematology analyzer calibration records, a review of the Complete Blood Count AcT Diff 2 Procedure, and an interview with the Laboratory Supervisor, the laboratory failed to perform calibrations at least every six months as per the laboratory's procedure. This was noted on two of four 2019-2021 AcT Diff 2 calibrations. The findings include: 1. A review of the AcT Diff 2 records revealed a calibration was performed on 12/20/2019; the next calibration was performed one year, three months later on 03/19/2021. 2. A review of the Complete Blood Count AcT Diff 2 Procedure revealed on page 4, "...Calibration when necessary or as required by regulatory agencies CLIA'88 requires calibration at least once every six months...". 3. During an interview on 01/12/2022 at 2:40 PM, the Laboratory Supervisor confirmed the laboratory failed to performed the calibrations due in June 2020 and December 2020.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the 2021 Hematology quality control (QC) records for the AcT Diff 2, the patient results log, and an interview with the Laboratory Supervisor and the Laboratory Director, the laboratory failed to ensure at least two levels of quality control were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted one day out of 6 months reviewed from March 2020 to June 2021. The findings include: 1. A review of the QC records for the AcT Diff 2 Hematology analyzer revealed on 06/28/2021 platelets were outside acceptable ranges for all 3 levels of QC (Low, Normal, and High). The background check for platelets also failed on the daily startup. 2. A review of the patient logs revealed ten patient CBCs (Complete Blood Count) were performed on 06/28/2021. 3. During an interview on 01/12/2022 at 2:40 PM, the Laboratory Supervisor and Laboratory Director confirmed QC was out of acceptable ranges for the background check and all three levels of controls for platelets.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of personnel records and an interview with the Laboratory Supervisor, the Technical Consultant failed to evaluate and document the performance of individuals at least annually after the first year of performing Complete Blood Counts (CBC's). This was noted on one out of two testing personnel for 2021. The findings include: 1. A review of personnel records revealed the annual performance was not evaluated or documented for Testing Personnel #1 for 2021. Testing Personnel #1's semiannual evaluation was performed on 10/22/2020 and an initial on the Sysmex XS-1000i (new CBC analyzer) was performed in August 2021 (when the new analyzer was put into use). 2. During an interview on 1/12/2022 at 2:40 PM, the Laboratory Supervisor confirmed Testing Personnel #1's annual evaluation (due in early 2021 for the Beckman Coulter AcT Diff 2, the previous CBC analyzer), was not performed or documented.