

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0679470	(X3) Date Survey Completed 04/05/2023
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 8007 Discovery Dr Suite A, Richmond, VA	
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
D0000	An announced CLIA recertification survey was conducted at Laboratory Corporation of America Holdings on March 5, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, review of procedures, and an interview, the laboratory failed to verify a non-graded Blood Cell Identification (BCI) result (1 of five) on their 2022 Hematology Module Event 3.</p> <p>1. Review of the laboratory's 2022 American Proficiency Institute (API) PT documentation (Events 1-3) revealed no evaluation or verification of accuracy for the non-graded challenge response for #BCI-14 on Event 3. API reported the score as "Not Graded, No Consensus". The inspector requested to review evaluation documentation for the challenge scored as not graded on the event outlined above. No evaluation documentation was available for review.</p> <p>2. Review of the laboratory's procedure manual revealed a procedure (title: Proficiency Testing Policy) that stated, "for all PT challenges that were intended to be graded but were not, PT performance must be assessed."</p> <p>3. An exit interview with the laboratory supervisor on 4/5/23 at approximately 2:30 PM confirmed the above findings.</p>
D5429	MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

A. Based on a review of manufacturer's operations manual, chemistry analyzer maintenance logs, field service preventative maintenance (PM) reports, lack of documentation, and an interview, the laboratory failed to document performance of required twice annual instrument preventative maintenance procedures during the twenty-two (22) months reviewed (timeframe: June 2021 - April 5, 2023). Findings include: 1. Review of the Roche Cobas Integra 400+ manual revealed manufacturer's instructions to "perform the following procedures at least twice annually: clean external water reservoir, clean fluid waste reservoir, clean internal water reservoir, clean wash station, clean instrument, replace ISE tubing" (under heading: Preventative Maintenance). 2. Review of the laboratory's chemistry maintenance logs from June 2021 to the date of the inspection on 04/05/23, revealed no documentation of the required semi-annual maintenance outlined above. The inspector requested to review documentation of the Cobas semi annual maintenance from June 2021 to 04/05/23. The laboratory supervisor stated on 04/05/23 at approximately 1:00 PM, "I can email our field service rep to get his PM reports. I believe he does those tasks at the time of his PM." 3. Review of the emailed PM reports revealed the following dates that a PM was performed by a field service rep: 2/26/21, 05/14/22, 01/11/23. The inspector noted that the PM's were documented once per year. 4. An exit interview with the laboratory supervisor on 4/5/23 at approximately 2:30 PM confirmed the above findings. B. Based on a review of manufacturer's operations manual, hematology analyzer maintenance logs, lack of documentation, and interviews, the laboratory failed to document performance of required instrument rotor valve cleaning and piercer replacement preventative maintenance procedures during the twenty-two (22) months reviewed (timeframe: June 2021 - April 5, 2023). Findings include: 1. Review of the hematology Sysmex XT-4000i manual revealed manufacturer's instructions to "perform rotor valve cleaning every 15,000 cycles, replace the piercer every 30,000 cycles". 2. Review of the laboratory's hematology maintenance logs from June 2021 to the date of the inspection on 04/05/23, revealed no documentation of the required cyclic maintenance outlined above. The inspector requested to review documentation of the Sysmex XT rotor valve cleaning and piercer replacement during the 22 months reviewed. The laboratory supervisor stated on 04/05/23 at approximately 1:30 PM, "I call Sysmex to find out if they have a record of that maintenance being completed." 3. The inspector inquired of the quality manager on 04/05/23 at approximately 2:00 PM if the rotor valve cleaning and piercer replacement maintenance alarms could be overridden/ignored once the cycle alarm was reached. The quality manager stated, "Yes, the personnel can over-ride the alarm. The maintenance chart should have documentation of the dates those procedures were performed." 4. An exit interview with the laboratory supervisor on 4/5/23 at approximately 2:30 PM confirmed the above findings.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of procedures, calibration verification records, lack of documentation, and interviews, the laboratory failed to perform linearity validation studies every six months for sixteen (16) of 16 analytes utilized for patient testing on the Roche Integra 400 chemistry analyzer according to policy during the review timeframe of June 2021 to the date of the inspection on April 5, 2023. Findings include: 1. Review of the laboratory's procedures revealed a policy to perform calibration verification at least once every six months (title: Laboratory Guideline Analytical Measurement Range). The policy stated "in order to maintain continued accuracy of quantitative laboratory measurements, verification of the analytical measurement range (AMR) is required at the specific interval is at least every 6 months". 2. Review of the laboratory's Roche Integra 400 chemistry test menu and procedures revealed the following 16 analytes utilized for patient testing were included in the linearity calibration verification guidelines outlined above: Albumin Alkaline Phosphatase Alanine Aminotransferase Aspartate Aminotransferase Blood Urea Nitrogen Calcium Chloride Carbon Dioxide Creatinine Glucose Lactate Dehydrogenase Magnesium Potassium Sodium Total Bilirubin Total Protein 3. Review of the laboratory's Roche chemistry analyzer calibration verification records for the 16 analytes outlined above during the timeframe of June 2021 to 04/05/23 revealed the following documentation: calibration verification by Maine Standards multi-level controls was performed/accepted by supervisor on 11/06/21, 07/29/22, and on 03/30/23. 4. The inspector noted that the AMR verification was performed once in calendar year 2022 requested to review additional documentation of calibration verification for the 16 analytes outlined above. No additional documentation was available. The laboratory supervisor stated on 04/05/23 at approximately 2 PM, "I recently took the leadership role and noted that the AMR verification was overdue. I did not get the studies finished until last week." 5. An exit interview with the laboratory supervisor on 4/5/23 at approximately 2:30 PM confirmed the above findings.