

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>34D0655109</p>	<p>(X3) Date Survey Completed</p> <p>05/10/2024</p>
<p>Name of Provider or Supplier</p> <p>Laboratory Corporation Of America Holdings</p>	<p>Street Address, City, State</p> <p>1126 North Church Street, Suite 104, Greensboro, NC</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the TC (technical consultant) 05/10/24, the laboratory failed to discard supplies that exceeded their expiration dates. Findings: During a tour of the laboratory at approximately 3:55 p.m., the surveyor observed the following expired supplies in a cabinet under the Integra 400 Plus chemistry analyzer, available for use: 1. 2 Reference electrodes lot # (10) 21522347, "Install before 2023-03-17" printed on box. 2. 1 Potassium electrode lot # (10) 31232947, "Install before 2024-04-26" printed on box. During the exit interview at approximately 5:25 p.m., the TC stated the expired supplies should have been discarded.</p>
<p>D6042</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2022 Prothrombin Time (PT) and</p>

Activated Partial Thromboplastin Time (PTT) quality control (QC) range establishment records, review of D-dimer QC package insert, review of 2022 and 2023 PT and PTT QC logs, and review of 2023 D-dimer QC logs 05/10/24, the TC failed to ensure the established ranges for new lot numbers of PTT and PT QC were entered correctly into the laboratory's LCLS computer system and manual QC log, and also failed to ensure the manufacturer's ranges for D-dimer QC were entered correctly into the laboratory's LCLS computer system and manual QC log. PT Level 3 QC was out of range for approximately 17 of 240 days reviewed, PTT Level 3 QC was out of range for approximately 40 of 240 days reviewed, and D-dimer Level Low QC was out of range for approximately 65 of 140 days reviewed. Findings: A. Review of laboratory policy "Sysmex CA and CS/BCS Series Reagents and Controls Lot Conversion Prothrombin Time, Activated Partial Thromboplastin Time, and Fibrinogen" Page 3, Section 5 revealed "Controls: Mean, SD and CV determination of new lot numbers a. 30 determinations for each level of control b. Process study over multiple days and stability limits of controls c. Calculate Mean, SD and CV". 1. The TC failed to ensure the established PT QC ranges for Citrol Level 3, Lot #556560, were entered correctly into the LCLS computer system and manual QC log, "CA-660 Coag QC Log". Review of 2022 PT QC range establishment records, "Quality Control Range Establishment Citrol Level 3", Lot #556560, dated 05/01/22 revealed an established range of 44.4 - 53.0 seconds (sec). The range in the LCLS computer system was 41.7 - 55.7 secs. The range entered on the manual QC log beginning in June of 2022 was 41.7 - 55.7 secs. The range entered on the manual QC log was changed in October 2022 to 38.7 - 58.7 secs and remained so until a new lot number range was established June 2023. Review of PT QC logs from June of 2022 through June of 2023 revealed the following dates in which the Citrol Level 3 QC was not within the established range of 44.4 - 53.0 secs: a. 5 of 22 days in June of 2022; 06/08 - 06/10 and 06/14 - 06/15. b. 6 of 20 days in July of 2022; 07/20 - 07/22 and 07/25 - 07/27. c. 5 of 21 days in October of 2022; 10/03 - 10/06 and 10/09. d. 1 of 20 days in February of 2023; 02/14. 2. The TC failed to ensure the established PTT QC ranges for Citrol Level 3, Lot #556560, were entered correctly into the LCLS computer system and on the manual QC log, "CA-660 Coag QC Log". Review of 2022 PTT QC range establishment records, "Quality Control Range Establishment aPTT Control Level 3", Lot #556560, dated 05/01/22 revealed an established range of 55.4 - 58.4 secs. The range in the LCLS computer system was 54.0 - 60.0 secs. The range entered on the manual QC log beginning in June of 2022 was 51 - 63 secs and remained so until a new lot number range was established June 2023. Review of PTT QC logs from June of 2022 through June of 2023 revealed the following dates in which the PTT Citrol Level 3 was not within the established range of 55.4 - 58.4 secs: a. 1 of 22 days in June of 2022; 06/13. b. 1 of 20 days in July of 2022; 07/13. c. 8 of 21 days in September of 2022; 09/07, 09/15 - 09/16 and 09/19 - 09/23. d. 11 of 21 days in October of 2022; 10/04 - 10/06, 10/09 - 10/13, 10/21, 10/24 and 10/28. e. 10 of 21 days in December of 2022; 12/02, 12/05. 12/12, 12/14, 12/19 - 12/20, 12/22, 12/27 and 12/29 - 12/30. f. 3 of 21 days in January of 2023; 01/06 and 01/26 - 01/27. g. 6 of 20 days in February of 2023; 02/07, 02/10, 02/14, 02/17, and 02/23 - 02/24. B. The TC failed to ensure the manufacturer's QC ranges for D-dimer Level Low, Lot #74414, were entered correctly into the LCLS computer system and on the manual QC log, "CA-660 D-Dimer QC Log". Review of manufacturer's package insert for "BIO-RAD Liquichek D-dimer Control Levels Low, 1, 2 and 3", Lot #74414, revealed a Level Low QC range of 0.313 - 0.470. The package insert included the handwritten notation "in use 6/1/23 pkg insert ranges". The range in the LCLS computer system was 0.19 - 0.39. The range entered on the manual QC log beginning June of 2023 was 0.29 - 0.49. The July 2023 QC log included a handwritten notation "ranges adjusted for July", but the ranges listed remained the same until January of

2024. Review of D-dimer QC logs from June of 2023 through December of 2023 revealed the following dates in which D-dimer Level Low QC was not within the manufacturer's range of 0.313 - 0.470: a. 14 of 18 days in June of 2023; 06/08 - 06/09, 06/13 -06/14, 06/19 - 06/24, and 06/27 - 06/30. b. 14 of 20 days in July of 2023; 07/03, 07/05 - 07/07, 07/11 - 07/14, 07/17 - 07/19, 07/20 - 07/21 and 07/24. c. 5 of 23 days in August of 2023; 08/02 - 08/04, 08/16 and 08/18. d. 6 of 20 days in September of 2023; 09/12 - 09/15 and 09/26 - 09/27. e. 6 of 20 days in December of 2023; 12/01, 12/05, 12/07 and 12/28 - 12/29.