Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2238389	10/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	7777 Hennessey Blvd, Ste 6000a, Baton Rouge, LA	

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	A Recertification survey was performed at Laboratory Corporation of America Holdings, CLIA ID 19D2238389, on October 21, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to document their evaluation of ungraded proficiency testing results for two (2) of five (5) events reviewed. Findings: 1. Review of the laboratory's "External Proficiency Testing Procedure" revealed the "The Laboratory Director or designee (documented) must review and sign the PT survey evaluation including: graded evaluation, ungraded evaluations including those ungraded due to lack of consensus, regulated and non-regulated challenges, and educational challenges." 2. Review of the laboratory's 2024 and 2025 American Proficiency Institute(API) proficiency testing records revealed the laboratory did not document their evaluation, to include acceptability, of "not graded" results for the following two (2) events: a) 2024 Chemistry Core 1st Event: Total Bilirubin, Samples: CH-02, CH-03, CH-05 b) 2025 Chemistry Core 2nd Event: Total Bilirubin, Samples: CH-07, CH-09, CH-10 3. In interview on October 21, 2025 at 1:30 pm, the Laboratory Director confirmed the acceptability of the ungraded proficiency testing results were not documented for the two (2) identified events.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish complete quality control (QC) procedures for Chemistry testing. Findings: 1. Review of the laboratory's "Quality Control Policy" revealed the laboratory did not include detailed written procedures for establishment of and adjustment to quality control ranges and corrective actions for unacceptable quality controls. 2. In interview on October 21, 2025 at 1:52 pm, the Laboratory Director stated the quality control policy that included QC establishment and adjustment to ranges was not implemented at this site. The Laboratory Director confirmed the laboratory's QC policies did not include the identified information.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, quality control (QC) records, corrective action logs, and interview with personnel, the laboratory failed to document complete corrective actions performed for unacceptable Chemistry QC for three (3) of seven (7) days reviewed in August 2025. Findings: 1. Review of the laboratory's "Quality Control Policy" revealed "The technologist must action any unacceptable QC with an appropriate comment in the vendor peer program (if one is available) and/or document the violation and corrective measures on the departmental corrective action log. If a

run is rejected, appropriate corrective measures should be performed. Corrective measures include; using a new bottle of QC, new reagent, performing a calibration and /or performing additional instrument maintenance. Refer to the instrument's Operator's Manual for additional troubleshooting details. Document the corrective measure(s) employed on the departmental corrective action log , when applicable, to include: a) Instrument Serial Number b) Date and Time of out-of-control value and/or corrective action c) Were any patients processed during the time of out-of-range controls and what was done with those patients (if any were processed while controls were out of range) d) Review Levy{sic} Jennings for shifts or trends e) Was the control repeated, and if so, was it the same vial of control or a new vial of control f) Any maintenance /troubleshooting performed to resolve the out-of-control value, if indicated. Document details g) Initials of name of the individual performing the investigation/corrective action" 2. Review of the laboratory's "Quality Control Corrective Action Log" had the following actions listed: "RSV=Repeated, same vial of control; RCAL=Recalibrated /Restandardized; RNV= Repeated, new vial of control; RNRG=Repeated, new reagents; RPQ3=Repeated, control within 3 SD." 3. Review of the laboratory's August 2025 Levey-Jennings reports and corrective action logs for Chemistry from August 11, 2025 through August 18, 2025 revealed documentation of corrective actions were not complete for the following: a) August 11, 2025: Alkaline phosphatase: MultiQual level 1: the initial value was 24 (flag 1-3s) at 7:02 am; the control was repeated nine (9) times. The final run of the control was at 15:28 with an acceptable value of 30. The laboratory documented "RSV" and "RCAL" as their corrective actions; however, the actions taken after each failed control were not documented. The laboratory did not document when the calibration occurred. Supervisor review was performed on September 26, 2025. Alkaline phosphatase: MultiQual level 3: the initial value was 276 (flag 1-3s) at 6:59 am; the control was repeated eighteen (18) times. The final run of the control was at 15:25 with an acceptable value of 292. The laboratory documented the initial value of the control as 286 at 7:00 am, which differed from the value and time on the "Levey-Jennings Report." The laboratory documented "RSV," "RCAL," and "changed lamp called service" as the corrective actions performed; however, the actions taken after each failed control were not documented. The laboratory did not document when the calibration and lamp change occurred and the outcome of the service call. Supervisor review was performed on September 26, 2025. Glucose: MultiQual level 3: the initial value was 356 (flag 1-2s) at 6:55 am; the control was repeated multiple times. The laboratory documented the initial value of the control as 353 at 7:00 am, which differed from the value and time on the instrument log. The laboratory documented their corrective actions as "RSV," RCAL," RNV," RNRG," and "changed lamp called service; " however, the actions taken after each failed control were not documented. The laboratory did not document when the calibration and lamp change occurred and the outcome of the service call. Supervisor review on September 26, 2025. b) August 14, 2025: Alkaline phosphatase: MultiQual level 3: the initial unacceptable value was 287 (flag 1-2s) at 7:04:55 am, with a repeated unacceptable value of 285 (flag 1-2s). The laboratory's documented initial outlier and repeat value differed from the "Levey-Jennings Report." The laboratory documented "RSV" and "low pack. took it off" as the corrective actions; however, the outcome of the pack removal was not documented. Supervisor review was performed on September 26, 2025. Aspartate aminotransferase: MultiQual level 3: the initial unacceptable value was 215 (flag 1-2s) at 7:06 am; the control was repeated five (5) times. The laboratory's documented initial outlier value differed from the "Levey-Jennings Report." The laboratory documented their corrective actions as "RSV" and "RCAL;" however, the actions taken after each failed control were not documented. Supervisor review was performed on September 26, 2025. c) August 15, 2025: Alanine transferase: MultiQual level 1: the initial unacceptable value was 25

	(flag 1-2s) at 7:04:49 am; the control was repeated four (4) times. The laboratory documented their corrective actions as "RSV" and "RCAL;" however, the actions taken after each failed control were not documented. The laboratory did not document when the calibration occurred. Supervisor review was performed on September 26, 2025. Alanine transferase: MultiQual level 3: the initial unacceptable value was 161 (flag 1-2s) at 7:01 am; the control was repeated nine (9) times. The laboratory's documented initial outlier value differed form the "Levey-Jennings Report." The laboratory documented their corrective actions as "RSV", "RCAL", and "RNV; " however, the actions taken after each failed control were not documented. Supervisor review was performed on September 26, 2025. 3. Further review of the laboratory's Levey-Jennings Report for August 2025 revealed the laboratory did not document corrective actions for quality control values that trended, defined in the laboratory's policy as "continuous deviation of data points in the same direction (above or below)." The Levey Jennings Report revealed all and/or majority of the QC values for the month of August 2025 falling below the mean for the following controls: MultiQual 1 for Alkaline phosphatase (fifty three (53) of fifty four (54) points fell below the mean) and MultiQual 3 for Alkaline phosphatase, Alanine transferase, Aspartate aminotransferase. 4, In interview on October 21, 2025 at 5:00 pm, the Laboratory Director and Testing Personnel 1 stated the Chemistry QC has had repeated failures for the past few months. The Laboratory Director and Testing Personnel 1 confirmed the laboratory did not document all the corrective actions taken for the identified QC failures.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing results are reviewed by the appropriate staff. Refer to D5221.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the Laboratory Director failed to ensure a complete quality control program was established to assure the quality of laboratory testing results. Refer to D5403.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever

	significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all corrective actions were documented when deviations from the laboratory's specifications occurred. Refer to D5781.