Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0999083	06/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	15655 Cypress Woods Medical Drive Suite 100, Houston, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's Roche Integra 400+ quality control (QC) records for the D-dimer coagulation test for February and March of 2022, review of random patient D-dimer test reports for the same interval and staff interview it was determined the laboratory failed to document performance of QC for coagulation D-dimer testing according to regulatory requirements (every 8 hours) for 6 of 20 reviewed patient reports where patient samples were tested beyond the required 8 hours QC interval. Findings included: 1. Review of the laboratory's Roche Integra 400+ QC records for

	the D-dimer coagulation test for February and March of 2022 revealed the laboratory performed D-dimer QC once each morning of patient testing. 2. Review of the laboratory's random patient D-dimer test reports for the same interval revealed the following 6 of 20 reviewed reports showed patients' samples were tested beyond the required 8 hours QC interval: Patient ID: 37401239 Sample tested: 02/09/2022 at 17:04 QC performed: 02/09/2022 at 06:46 Elapsed interval: 10 hours 18 minutes Patient ID: 47798152 Sample tested: 02/16/2022 at 16:26 QC performed: 02/16/2022 at 06:48 Elapsed interval: 9 hours 22 minutes Patient ID: 991897748 Sample tested: 02/17/2022 at 16:16 QC performed: 02/17/2022 at 06:27 Elapsed interval: 9 hours 49 minutes Patient ID: 05361787 Sample tested: 03/22/2022 at 16:50 QC performed: 03/22/2022 at 06/36 Elapsed interval: 10 hours 14 minutes Patient ID: 99251258 Sample tested: 03/30/2022 at 16:18 QC performed: 03/30/2022 at 06:46 Elapsed interval: 9 hours 32 minutes Patient ID: 93494698 Sample tested: 03/30/2022 at 16:19 QC performed: 03/30/2022 at 06:46 Elapsed interval: 9 hours 31 minutes 3. In an interview on 06/06/2022 at 1200 hours in the conference room the Technical Supervisor number 2 (as described on submitted Form 209 signed by laboratory director on 06/06/2022) confirmed the findings.
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 temperature logs for February to May of 2022, review of laboratory's policies and staff interview it was determined the laboratory failed to document corrective action for 8 of 8 instances corrective action was needed for temperature that was out of laboratory's defined range. Findings included: 1. Review of the laboratory's temperature logs revealed the laboratory documented minimum, maximum and current temperatures where the acceptability ranges were defined as follows: Freezer : (-50)-(-20)C Tech-Refrigerator: 4-8C Room: 18-25C 2. Further review of the laboratory's temperature logs for February to May of 2022 revealed the documented room temperature was out of laboratory's defined acceptability range as follows: Freezer: Date: 02/12/2022 Recorded maximum: -19C Acceptable maximum: -20C Tech-Refrigerator: Date: 03/09/2022 Recorded maximum: 9C Acceptable maximum: 8C Date: 03/10/2022 Recorded maximum: 9C Acceptable maximum: 8C Room: Date: 02/07/2022 Recorded maximum: 25.2C Acceptable maximum: 25C Date: 02/14/2022 Recorded maximum: 25.5C Acceptable maximum: 25C Date: 04/11/2022 Recorded maximum: 27.7C Acceptable maximum: 25C Date: 04/25/2022 Recorded maximum: 28.6C Acceptable maximum: 25C Date: 05/16/2022 Recorded maximum: 28.7C Acceptable maximum: 25C 3. The laboratory was asked to provide documentation of corrective action for the out of range temperatures and no such documentation was available for review prior to survey exit. 4. In an interview on 06/09/2022 at 10:30 hours in the conference room the

	laboratory's Technical Supervisor number 2 (as described on submitted Form 209, signed by laboratory director on 06/06/2022) confirmed the findings.