Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2129433	09/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	1705 S Fm 51 Suite 108, Decatur, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of verification studies for Pathfast analyzer, laboratory records, and confirmed in interview, the laboratory failed to ensure the reportable range for NT-proBNP analyte was verified by the laboratory's studies. Findings: 1. According to

	verification studies, the laboratory added the NT-proBNP analyte to the Pathfast analyzer test menu on 06/2021. 2. Review of verification studies for the Pathfast analyzer revealed the laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies for chemistry analytes as required by 493.1253 as follows: Reportable range from verification study NT-proBNP: 20.8-24,500 pg/mL Laboratory reportable range: NT-proBNP: 15.00-30,000 pg/mL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. 3. Review of laboratory records revealed the laboratory had an annual test volume of 62 NT-proBNP tests. 4. During an interview on 09/07/2021 at 12:30 pm, the laboratory director confirmed the above findings. Word Key: NT-proBNP- N-terminal-pro B-type Natriuretic Peptide
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, quality control (QC) records, and confirmed in interview, the laboratory failed to establish the statistical parameters for unassayed materials used on the Pathfast analyzer for 2 of 2 lots of QC in 2020 for the CKMB analyte and 2 of 2 lots in 2021 for the D-Dimer analyte. Findings: 1. Review of the laboratory policy titled "QUALITY CONTROL POLICY AND QUALITY CONTROL IN USE" page 2 stated: "PROCEDURE Quantitative Assays ... 8. When new lots of unassayed control material are introduced the new lot is run in parallel with the old lot to give at least 20 values for each level. The control means and standard deviation are calculated and reviewed and accepted or rejected by the Technical Supervisor. If the study is accepted the mean and standard deviation from the new lot is entered into the computer. Exception: Any instructions issued by LabCorp Science and Technology in a bulletin (Quality Control Updates QCU) supersede the instructions listed above." 2. Review of BioRad Liquichek Cardiac Markers Plus Control LT package insert revealed: "ASSINGMENT OF VALUES The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product ...It is recommended that each laboratory establish its own acceptable ranges and use those provided as guides." Review of BioRad Liquichek D-dimer Control package insert revealed: "ASSINGMENT OF VALUES The mean values provided in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for each lot of product ... Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during

	the life of this control ... It is recommended that each laboratory establish its own acceptable ranges and use those provided as guides." 3. Review of BioRad Control package inserts and CKMB and D-Dimer QC data revealed the laboratory was utilizing the range of means from the package insert for the acceptability of QC. The laboratory did not establish means and limits for each parameter for the following lots: CKMB Level 1 Lot 67611, expiration date: 10/31/2021, date put into use: 11/09 /2020 Level 2 Lot 67613, expiration date: 10/31/2021, date put into use: 08/25/2020 D-Dimer Level 1 Lot 17004, expiration date: 05/31/2023, date put into use: 03/01 /2021 Level 2 Lot 17001, expiration date: 05/31/2023, date put into use: 03/01/2021 4. During an interview on 09/07/2021 11:45 am, the laboratory director stated that the laboratory did not establish its own mean and ranges for CKMB and D-Dimer analytes and she only verified the ranges provided by the manufacturer. She further stated that the package inserts were used for QC acceptability. This confirmed the above findings. Word Key: CKMB- creatine kinase-MB
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 review of laboratory policy, manufacturer's instructions, Medica EsayRA quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results for 4 of 4 patients in 2021 (August). Findings: 1. Review of the laboratory's policy "QUALITY CONTROL POLICY AND QUALITY CONTROL IN USE" revealed: "PROCEDURE Quantitative Assays ... 4. Control material is treated in the same manner as patient samples and run in accordance with regulatory agencies. 5. All out of limits control values (QC exceptions) must be resolved and documented before releasing patient results." 2. Review of Medica EasyRA instructions for use for carbon dioxide (CO2) and lipase revealed: "Quality Control It is recommended that two levels of human serum based controls (normal and abnormal) be run with the assay at least once every 8 hours and with each reagent lot change. Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction, or procedural errors. The laboratory should also follow local, state, and federal quality control guidelines when using quality control materials." 3. Review of Medica EasyRA QC records revealed QC was not within acceptable range before reporting patient test results for the following days in August 2021: QC level A control lot #20266; expiration date: 08/30/2023 QC level B control lot #20267; expiration date: 08/30/2023 CO2 acceptable ranges: Level A control: 3.2-9.2 mmol/L Level B control: 12.2-22.2 mmol/L Lipase acceptable ranges: Level A control: 159.5-189.5 U/L Level B control: 488.8-568.8 U/L 08/23/2021 Lipase level B control: 9:56 am: 482.0 U/L; QC failed and was repeated 10:07 am: lipase QC was repeated but the run was canceled prior to the completion of the run Corrective action stated, "QC did not have Rejed [sic] code on LCWS so cancelled rerun of LIP". The result for lipase level B control was not within acceptable range and 1 patient was tested and reported: Sample ID: 23582300020 08/25/2021 CO2 level A control 8:36 am: 9.4 mmol/L; QC failed and was not repeated Corrective action stated, "CO2 did not flag in LCWS. 12s." The result for CO2 level A control was not within acceptable range and 1 patient

	was tested and reported: Sample ID: 23782300010 08/26/2021 CO2 level A control 8: 36 am: 9.3 mmol/L; QC failed and was not repeated Corrective action stated, "CO2 1.2 s NO flag". The result for CO2 level A control was not within acceptable range and 2 patients were tested and reported: Sample ID: 23882300040, 23882300020 The laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results. 4. During an interview on 09/08/2021 at 2:10 pm, the Laboratory Director stated that QC was not repeated because the laboratory used modified Westgard rules in their quality control program and a "12s rule" did not require a repeat, confirming the above findings.