

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0683724	<b>(X3) Date Survey Completed</b>  06/15/2023
<b>Name of Provider or Supplier</b>  Laboratory Corporation Of America	<b>Street Address, City, State</b>  1401 Harrodsburg Rd B 195, Lexington, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was initiated on 06/15/2023. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, and staff interview; the laboratory failed to monitor and document room temperature for 3 of 3 storage areas. Findings included: 1. Observed on 06/15/2023 at 3:00 p.m. were the following three areas in the laboratory where Becton Dickinson (BD) blood collection tubes were stored: a. Hallway closet; Six (6) packs of one hundred (100) BD Vacutainer K2 Ethylenediaminetetraacetic Acid (EDTA) blood collection tubes, Lot Number 2227128; thirteen (13) packs of one hundred (100) BD Vacutainer Serum Separator Tubes (SST) blood collection tubes, Lot Number 3075122 b. Blood Drawing Room #2 Twenty-four (24) BD Vacutainer K2 EDTA collection tubes c. Blood Drawing Room #3 Fourteen (14) BD Vacutainer K2 EDTA collection tubes Forty-four (44) BD Vacutainer SST collection tubes No temperature monitoring devices were observed in the three rooms. 2. The manufacturer's instructions on the label of each package of the BD blood collection tubes stated a storage requirement of 4 degrees Celsius (39.2 degrees Fahrenheit) to 25 degrees Celsius (77 degrees Fahrenheit). 3. In an interview</p>

on 06/15/2023 at 3:35pm, the General Supervisor stated that the temperature was not monitored. This confirmed the findings.

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on the manufacturer's instructions, direct observation, and interview with the General Supervisor, the laboratory failed to label one of nine in-use reagents with open and revised expiration dates. a. Review of the manufacturer's instructions titled, "Calibrator for automated systems cobas", stated on page 1, "Stability of the components in the reconstituted calibrator: at 2-8C 2 days." b. A sampling of calibration reagents observed stored in the refrigerator included: 1. 1 open bottle of C. f.a.s. (Calibrator for automated systems) Calibrator, Lot number 1075350 The laboratory failed to label the bottle with open and revised expiration dates specified by the manufacturer (for 2 days). c. In an interview on June 15, 2023 at 3:09 PM in the laboratory, the General Supervisor confirmed the findings. \*Word Key: C=degrees Celsius

**D5783**

CORRECTIVE ACTIONS  
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's chemistry quality control (QC) records, patient test reports, and interview with the General Supervisor, the laboratory failed to evaluate patient test results generated since the last acceptable quality control for 7 of 150 days in January to May 2023 on the Roche Integra 400. Findings Included: a. A review of the laboratory's QC and corrective action documentation revealed: 1. 01/09/2023 Analyte: Pediatric Bilirubin, Direct Control Name: BIORAD LIQUICHEK LEV 01 Comments: "Neonatal Direct Bilirubin P1 and P2 - 3S Violation for both ..." Last acceptable QC: 01/06/2023 Total volume of specimens processed: 3 2. 01/18/2023 Analyte: Creatinine Control Name: BIORAD LIQUICHEK LEV 01 Comments: "Calibrate Creatinine C2 3s violation" Last acceptable QC: 01/17/2023 Total volume of specimens processed: 29 3. 01/20/2023 Analyte: Creatinine Control Name: BIORAD LIQUICHEK LEV 01 Comments: "Calibrate Creatinine C2 2s violation" Last acceptable QC: 01/19/2023 Total volume of specimens processed: 51 4. 05/03/2023 Analyte: LDH Control Name: BIORAD LIQUICHEK LEV 01

Comments: "LDH C1 2-2s Repeat..LDH C1 3s Calibrate and Repeat" Last acceptable QC: 05/02/2023 Total volume of specimens processed: 3 5. 05/11/2023 Analyte: Alkaline Phosphatase Control Name: BIORAD LIQUICHEK LEV 01 Comments: "Alkaline Phosphatase C2 3s Repeat" Last acceptable QC: 05/10/2023 Total volume of specimens processed: 54 6. 05/18/2023 Analyte: HDL Cholesterol Control Name: BIORAD LIQUICHEK LEV 01 Comments: "HDL C2 2s Repeat..HDL C2 2s Calibrate and Repeat" Last acceptable QC: 05/17/2023 Total volume of specimens processed: 28 7. 05/24/2023 Analyte: Uric Acid Control Name: BIORAD LIQUICHEK LEV 01 Comments: "Uric Acid C2 2s Repeat..Uric Acid C2 2s Calibrate and Repeat" Last acceptable QC: 05/23/2023 Total volume of specimens processed: 2 b. An interview with the General Supervisor on 6/15/2023 at 11:50AM in the office confirmed these findings.