

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2306122	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Laboratory Corporation Of America Holdings, Inc	Street Address, City, State 329 N Hall Road, Alcoa, TN	
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Citation One: Based on direct observation, a review of the manufacturer's storage requirements, a lack of documentation, and staff interviews, the laboratory failed to ensure proper temperature control for Roche Cobas C Systems Chemistry reagents on the survey date, 09.02.2026. The findings include: 1. Observation of the laboratory on 09.02.2026 at 8:00 a.m. revealed a Roche Cobas Pure chemistry analyzer, serial number 7320-05, used for ALB, ALP, ALT, AST, BUN, CA, CO2, CREAT, GLUC, CL, K, NA, TBILI, TP, MG, and PHOS patient testing. An observation of the Network and Supply closet, identified as 1094C, revealed the following chemistry reagents available for use with the Roche Cobas Pure analyzer. - 2 2L Cobas C Systems, Acid Wash (Detergent 2), reference number 08302723190, lot number 92242301, expiration date 08.31.2027 - 6 2L Cobas C Systems, Basic Wash (Detergent 1), reference number 08302545190, lot number 94843301, expiration date 01.31.2028 - 8 2000mL Cobas C Systems, ISE Internal Standard Gen 2, reference number 04880455190, lot number 96042601, expiration date 02.29.2028. - 8 2000mL Cobas C Systems, ISE Diluent Gen 2, reference number 04880480190, lot number 96411801, expiration date 03.31.2028. 2. A review of the Cobas C Systems manufacturer's storage requirements revealed that the acceptable temperature range

for reagent storage is 15C to 25C. 3. A request for environmental records for the Network and Supply closet 1094C revealed no records available for surveyor review on the survey date, 09.02.2026. 4. An interview with technical consultant number two (TC2) on 09.02.2026 at 8:15 a.m. confirmed the above survey findings. Word Key: C = degrees Celsius mL = milliliters L = liters ISE = Ion-Selective Electrodes ALB = Albumin ALP = Alkaline phosphate ALT = Alanine Aminotransferase AST = Aspartate Aminotransferase BUN = Urea Nitrogen CA = Calcium CO2 = Carbon Dioxide CREAT = Creatinine GLUC = Glucose CL = Chloride K = Potassium NA = Sodium TBILI = Total Bilirubin TP = Total Protein MG = Magnesium PHOS = Phosphorus Citation Two: Based on direct observation, a review of the manufacturer's storage requirements, a lack of documentation, and staff interviews, the laboratory failed to ensure proper temperature control for blood collection tubes in the supply area and the phlebotomy collection area on the date of the survey, 09.02.2026. The findings include: 1. Observation of a closed-door supply closet, identified as 1206A, on 09.02.2026 at 8:20 a.m. revealed the following blood collection tubes stored in the closet: - 4 packs, containing 100 tubes per pack Becton Dickinson (BD) Vacutainer 4.0 mL dipotassium Ethylenediaminetetraacetic Acid (K2E) tubes, reference number 367861, lot number 6104237, expiration date 08.31.2027. - 3 packs, containing 100 tubes per pack BD Vacutainer 3.0mL Gel and Lithium Heparin (LH) tubes, reference number 367960, lot number 6013801, expiration date 01.31.2027. - 1.5 packs, containing 100 tubes per pack BD Vacutainer 2.7mL Buffered Sodium Citrate (9NCL) tubes, reference number 363083, lot number 6047458, Expiration number 11.30.2026. - 3 packs, containing 100 tubes per pack, BD Vacutainer 3.5mL Serum Separator Tube (SST) tubes, reference number 367983, lot number 6072616, expiration date 02.28.2027. - 2 packs, containing 100 tubes per pack, BD Vacutainer 8.5mL Serum Separator Tube (SST) tubes, reference number 367988, lot number 6120186, expiration date 04.30.2027. - 1 pack, containing 100 tubes per pack, BD Vacutainer 10.0mL Serum Blood Tube, reference number 367820, lot number 5275771, expiration date 09.30.2027. Observation of the blood collection room on 09.02.2026 at 8:25 a.m. revealed three blood collection stations, with the following blood collection tubes stored on the tables beside the phlebotomy chairs: - 45 BD Vacutainer 4.0mL K2E tubes - 55 BD Vacutainer 3.0mL Gel and Lithium Heparin (LH) - 35 BD Vacutainer 3.5mL Serum Separator Tube (SST) - 40 BD Vacutainer 8.5 mL Serum Separator Tube (SST) 2. A review of the BD Vacutainer manufacturer's storage requirements revealed that the acceptable temperature range for tube storage is 4C to 25C. 3. A request for environmental records for supply closet 1206A and the blood collection room revealed no records available for surveyor review on the survey date, 09.02.2026. 4. An interview with technical consultant number one (TC1) on 09.02.2026 at 8:30 a.m. confirmed the above survey findings. Word Key: C = degrees Celsius mL = milliliters