Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463125	11/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	8415 Goodwood Boulevard, Suite 103, 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 Certification survey was performed on November 7, 2022 at Laboratory Corporation of American Holdings, CLIA ID # 19D0463125. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: *** Repeat deficiency from survey conducted on March 24, 2021 *** I. Based on review of the laboratory's policies, manufacturer's instructions, patient instrument printouts, patient final reports, and interview with personnel, the laboratory failed to follow manufacturer's instructions for complete blood count (CBC) instrument flags for two (2) of five (5) patients reviewed. Findings: 1. Review of the laboratory's "Abbott Cell Dyn Ruby for CBC with auto diff" policy revealed "Manual review of smears is required to confirm or qualify abnormal results or to evaluate WBC, RBC, and/or Platelet morphology." 2. Further review of the laboratory's "Abbott Cell Dyn Ruby for CBC with auto diff" policy revealed "All results with flags listed in the chart below will be repeated and the repeat noted on the report for the following: Descriptor: NWBC WBC VAR LYM FWBC DFLT (NLMEB) WBC NRBC/RRBC DFLT (NLMEB) MCHC BAND IG BLAST VAR LYM RBC MORPH Plt Clump LRI (low range interference) LURI NOC and WOC flags Action taken: "Rerun specimen and note results repeated on report." 3. Review of the manufacturer's instructions revealed the following actions: RBC MORPH: "Review a stained smear

	for abnormal RBC or PLT morphology and follow your laboratory's review criteria. If NRBC or RRBCs are suspected to be present, run the specimen in the CBC+RRBC test selection." 4. Review of instrument printouts and patient final test reports revealed the following two (2) patients did not have a manual smear performed per manufacturer's instructions for the identified flags: October 3, 2022: Patient G0013731 Flag: RBC MORPH October 3, 2022: Patient G0013726 Flag: RBC MORPH 5. In interview on November 7, 2022 at 9:40 am, the Technical Consultant stated if there are instrument flags for CBC results the sample is retested and if the flag repeats then it is sent to a local hospital for manual slide review. 6. In further interview on November 7, 2022 at 11:38 am, the Technical Consultant confirmed the identified patients with repeated flag results did not have a manual smear review performed per manufacturer's requirements. II. Based on observation by surveyor, review of the manufacturer's package insert, and interview with personnel, the laboratory failed to document the visual inspection of blood culture bottles prior to use per manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on November 7, 2022 at 9:57 am revealed the laboratory utilizes BacT /ALERT Adult and Pediatric Blood Culture Collection Kits. 2. Review of the manufacturer's package insert revealed "Inspect each blood culture bottle before use to ensure integrity of bottle and sensor on bottom of bottle is intact. The sensor is normally a uniform grayish-green color and a yellow color would indicate contamination of the broth. Discard any bottle found to be damaged or with a sensor that is yellow." 3. In interview on November 7, 2022 at 2:12 pm, the Technical Consultant confirmed the laboratory does not document visual inspections of the blood culture bottles received.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: *** Repeat deficiency from survey conducted on March 24, 2021 *** Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5411 I and D5411 II.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5411 I and D5411 II.