Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0462635	07/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	12525 Perkins Road, Suite C, 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 Recertification survey was performed at Laboratory Corporation of America Holdings, CLIA ID 19D0462635, on July 24, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, manufacturer's instructions, patient instrument printouts, patient final test reports, and interview with personnel, the laboratory failed to follow their policy for complete blood count (CBC) instrument flags for four (4) of six (6) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 24, 2024 at 9:01 am revealed the laboratory utilizes the Sysmex XS-1000 i for CBC testing. 2. Review of the laboratory's "Hematology Specimen Confirmation" policy revealed the following: a) "All CBC/diff parameters will be reviewed for flags." b) " Any parameters with flags will be repeated. Note results were repeated on the report. If flags remain after repeat, the the entire CBC will be sent to the reference laboratory for testing. Do not report any CBC results. Notify client in the event testing needs to be sent out to let them know that the results will be delayed." 3. Review of the manufacturer's "Flagging Interpretation Guide" revealed the "asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting. This may include scanning a peripheral smear or performing a manual differential." 4. Review of random selection of patient instrument printouts and final

	test reports revealed the following patients' repeated results had instrument flags and were not sent to a reference laboratory for further testing: a) June 28, 2023: Patient 3725127; Flags: "Atypical Lympho?" and "HGB Defect?"; asterisk (*) next to the results for neutrophils, lymphocytes, and monocytes b) April 12, 2024: Patient 4341082; Flags: "Blasts?;" asterisk (*) next to the results for neutrophils, lymphocytes, and monocytes c) April 19, 2024: Patient 4151450; Flags: "Atypical Lympho?" and "HGB Defect?;" asterisk (*) next to the results for neutrophils, lymphocytes, and monocytes d) April 30, 2024: Patient 4206787; Flags: "Immature Gran?" and "Atypical Lympho? ;" asterisk (*) next to the results for neutrophils, lymphocytes, monocytes, eosinophils, and basophils 5. In interview on July 24, 2024 at 12:21 pm, the Laboratory Director stated the identified patient samples were not sent out to a reference lab for further testing.
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: 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 D5401.