Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463125	03/24/2021
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	An Initial survey was performed on March 24, 2021 at Laboratory Corporation of America Holdings, CLIA ID # 19D0463125. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and personnel records, the laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant were followed. Findings: 1. Review of the laboratory's "Competency Assessment Policy" revealed "Employees who fulfill the following roles as outlined by CLIA must have competency assessed based upon their regulatory responsibilities in addition to any testing responsibilities they may have such as: Clinical Consultant (CC), Technical Consultant (TC), Technical Supervisor (TS), General Supervisor (GS), Testing personnel. Competency for non-waived tests is assessed at the following times: a) after training, b)semi-annually during the first year, c) Annually after the first year." 2. Review of personnel records for the Clinical Consultant revealed no documentation of a competency assessment for his duties as Clinical Consultant. 3. In interview on March 24, 2021 at 10:40 am, Testing Personnel 1 confirmed the Laboratory Director did not perform a competency assessment for the Clinical Consultant.
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 review of the laboratory's procedures, manufacturer's instructions, and interview with personnel, the laboratory failed to establish complete written policies for Complete Blood Counts (CBC) flags. Findings: 1. Review of the laboratory's "Abbott Cell-Dyn Ruby: Complete Blood Count with a 5-Part Differential" procedure and manufacturer instructions revealed the laboratory did not include the following: a) Complete Blood Counts (CBC) flagging issues that may occur on the Cell-Dyn Ruby, to include what alternate methods/actions are required per the manufacturer 2. In interview on March 24. 2021 at 12:12 pm, Testing Personnel 1 confirmed the laboratory's policies did not include a complete list of actions for flags per manufacturer requirements.
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: Based on observation by surveyors, review of the manufacturer's instrument manual, laboratory procedures, patient test results, and interview with personnel, the laboratory failed to follow manufacturer's instructions for flags appearing on Complete Blood Counts (CBC) for two (2) of two (2) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on March 24, 2021 at 9:28 am revealed the laboratory utilizes the Cell Dyn Ruby for CBC testing. 2. Review of the laboratory's "Abbott Cell-Dyn Ruby: Complete Blood Count with a 5-Part Differential" procedure and manufacturer's instrument manual revealed the laboratory did not include a complete list of flags identified by the manufacturer. 3. Review of the laboratory's "Abbott Cell-Dyn Ruby: Complete Blood Count with a 5-Part Differential" procedure "Interpretation of Results" section revealed "When receiving suspect differential flags, check specimen for clots or agglutination and re-run specimen; redraw if necessary. If the flag persists, make two blood smears, order an Outreach Lab Slide Review, and forward to the Core Lab for verification." 4. In interview on March 24, 2021 at 9:53 am, the Testing Personnel 1 stated patient samples with CBC flags are sent to main hospital. 5. Review of the manufacturer's instrument manual revealed the following actions: a) "Blast*: Review a stained smear for the presence of blasts and follow your laboratory's review criteria." b) "RBC Morph*: 1. Review a stained smear for abnormal RBC or PLT morphology and follow your laboratory's review criteria. 2. If NRBC or RRCs are suspected to be present, run the specimen in the CBC+RRBC test selection." 6. Review of the following two (2) patients revealed the laboratory reported the flagged results without further action: a) November 30, 2020: Patient G0002727; Flags: Blasts, and RBC

	Morphology" b) December 3, 2020: Patient G002799; Flags: Blasts The laboratory did not have documentation of the identified samples being retested or sent to a reference laboratory for smear review. 7. In interview on March 24, 2021 at 12:12 , the Laboratory Director stated the laboratory could not show the identified patients were sent to a reference laboratory for further testing. The Laboratory Director confirmed the laboratory reported the flagged results for the identified patients.
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 direct observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5411.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, CMS-209 form, personnel records, and interview with personnel, the Laboratory Director failed to ensure competency of testing personnel was performed by the Technical Consultant. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the Laboratory Director serves as the Technical Consultant. 2. Review of the laboratory's job description for the Technical Consultant revealed the following responsibility: "Evaluates the competency of all testing personnel and assures that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently." 3. Review of personnel records for Testing Personnel 1 revealed the 2020 competency assessment was performed by a testing personnel from a sister laboratory, not the Technical Consultant on October 24, 2020. The Laboratory Director signed the competency assessment on November 2, 2020. 4. In interview on March 24, 2021 at 10:27 am, the Laboratory Director confirmed a testing personnel from a sister laboratory performed the competency assessment for Testing Personnel

	1. The Laboratory Director stated she signed off on the competency assessment after its completion. II. Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5401.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Clinical Consultant. Findings: 1. Review of personnel records for the Clinical Consultant revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Clinical Consultant. 2. In interview on March 24, 2021 at 10:40 am, Testing Personnel 1 confirmed she did not have written documentation of delegation of responsibilities to the Clinical Consultant.