Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0462635	03/23/2021
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	An Initial survey was performed on March 23, 2021 at Laboratory Corporation of America Holdings, CLIA ID # 19D0462635. 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 23, 2021 at 11:47 am, the Laboratory Director confirmed she 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 policies, 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 "Cell-Dyn Emerald Action" and manufacturer instructions revealed the laboratory did not include the following: a) Complete Blood Counts (CBC) flagging issues that may occur on the Emerald, to include what alternate methods/actions are required per the manufacturer 2. In interview on March 23. 2021 at 12:34 pm, Testing Personnel 1 confirmed the laboratory's policies did not include actions for flags per manufacturer requirements.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have complete policies and procedures for quality control (QC) for Complete Blood Count (CBC) testing. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include frequency of performance, when and how to assess patients after failed QC for CBC testing. 2. In interview on March 23, 2021 at 11:56 am, Testing Personnel 1 stated the laboratory changed the number of times QC is performed due to extended clinic hours stopping. Testing Personnel 1 confirmed the laboratory's polices did not include the identified information.
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 policies, patient test results, and interview with personnel, the laboratory failed to follow manufacturer's instructions for flags appearing on Complete Blood Counts (CBC) for three (3) of three (3) patients reviewed. Findings: 1. Observation by surveyors during the laboratory tour on March 23, 2021 at 9:47 am revealed the laboratory utilizes the Cell Dyn Emerald for CBC testing. 2. Review of the laboratory's "Cell-Dyn Emerald Action Limits"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 "Reporting of Results" policy revealed "For all parameters that are referred to the main lab add result comments: 'Verified by repeat' and 'Automated Differential contains suspect flags. Specimen sent to Core Lab for verification.' " 4. In interview on March 23, 2021 at 12:34 pm, Testing Personnel 1 and Testing Personnel 2 stated patient samples with CBC flags are sent to a neighboring hospital. 5. Review of the manufacturer's instrument manual revealed the following actions for "WBC Flags": a)" L1: check the specimen for clots or agglutination,. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count Redraw and retest the specimen as required." b)" L2: check the specimen for clots or agglutination,. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the sample as required." c)" L3: check the specimen for clots or agglutination,. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." d) "L5: check the specimen for clots or agglutination,. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required." 6. Review of the following three (3) patients revealed the laboratory reported the flagged results without further action: a) January 11, 2021: Patient 1863084; Flags: L1, :3, L5 b) March 1, 2021: Patient 2343127; Flags: L2, L3 c) March 5, 2021: Patient 2828914; Flag: L5 The laboratory did not have documentation of the identified samples being sent to neighboring hospital. 7. In interview on March 23, 2021 at 12:55 pm, Testing Personnel 1 confirmed the flagged lab results for the identified patients were reported.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of temperature logs, laboratory policies, and interview with personnel, the laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained between 2 to 8 degrees Celsius for 177 days of 212 days reviewed. Findings: 1. Review of the laboratory's "Temperature Monitoring" policy revealed "Temperature logs are reviewed monthly by a supervisor

	or designee for compliance. The review includes checks that all daily temperatures have been recorded and that all temperatures are within range, or that corrective action has been taken and properly documented." 2. Review of the laboratory's temperature logs from August 2020 through February 2021 revealed the refrigerator's max temperature was documented outside of the acceptable limits without documented corrective actions for the following dates: a) August 1, 2020 through August 23, 2020 documented "high temp" 8.05 degrees Celsius b) September 22, 2020 through September 30, 2020 documented "max" temperatures 8.05 degrees Celsius c) October 1, 2020 through October 31, 2020 documented "max" temperatures 8.05 degrees Celsius d) November 1, 2020 through November 30, 2020 documented "max" temperatures 8.05 degrees Celsius, exception November 26, 2020 and November 28, 2020 laboratory closure e) December 1, 2020 through December 31, 2020 documented "max" temperatures 8.05 degrees Celsius, exception December 25, 2020 laboratory closure f) January 2, 2021 through January 31, 2021 documented "max" temperature 8.05 degrees Celsius g) February 1, 2021 through February 21, 2021 documented "max" temperatures 8.05 degrees Celsius, exception February 15, 2021 and February 16, 2021 laboratory closure h) February 22, 2021 through February 28, 2021 documented "max" temperatures 8.05 degrees Celsius 3. In interview on March 23, 2021 at 11:50 am, the Laboratory Director confirmed the laboratory did not perform corrective actions for the identified dates.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to establish complete written policies for Complete Blood Counts (CBC) flags. Refer to D5401. 2. The laboratory failed to have complete policies and procedures for quality control (QC) for Complete Blood Count (CBC) testing. Refer to D5403. 3. The laboratory failed to follow manufacturer's instructions for flags appearing on Complete Blood Counts (CBC) for three (3) of three (3) patients reviewed. Refer D5411. 4. The laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained between 2 to 8 degrees Celsius for 177 days of 212 days reviewed. Refer D5785.
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.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5791.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D5785.
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: 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. Findings: 1. The laboratory failed to establish complete written policies for Complete Blood Counts (CBC) flags. Refer to D5401. 2. The laboratory failed to have complete policies and procedures for quality control (QC) for Complete Blood Count (CBC) testing. Refer to D5403.
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 23, 2021 at 11:47 am, the Laboratory Director confirmed she did not have written documentation of delegation of responsibilities to the Clinical Consultant.