Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0959085	03/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	4950 Essen Lane, Fifth Floor, 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 26, 2021 at Laboratory Corporation of America Holdings, CLIA ID # 19D0959085. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to retain instrument printouts for Complete Blood Counts (CBC) testing for at least two (2) years. Findings: 1. Review of the laboratory's policies revealed the following: a) "Retention of Laboratory Records and Materials: The laboratory maintains all reports and records in accordance with the regulatory standards of CLIA and JCAHO, All Quality Control and Calibration records and worksheets., Quality Assurance and Safety records/documentation , are kept on hand for 2 years." 2. Review of the laboratory's Change of Ownership forms revealed the laboratory obtained a Certificate of Compliance on July 13, 2020. 3. In interview on March 26, 2021 at 10:12 am, Testing Personnel 1 stated the laboratory does not back up the Cell-Dyn (CBC analyzer). Testing Personnel 1 further stated the laboratory can not retrieve any instrument data prior to January 2021. II. Based on record review and interview with personnel, the laboratory failed to retain calibration records for one (1) of two (2) calibrations reviewed in 2020 for the Cell-Dyn Ruby analyzer for at least two (2) years. Findings: 1. Review of the laboratory's policies revealed the following: a) "Retention of Laboratory Records and Materials: The laboratory maintains all reports and records in accordance with the regulatory standards of CLIA and JCAHO, All

	Quality Control and Calibration records and worksheets., Quality Assurance and Safety records/documentation , are kept on hand for 2 years." 2. Review of the laboratory's "Calibration Verification" policy revealed "System calibrations must be validated at least every 6 months, at changes in instrumentation and when complete change in reagents for a procedure is introduced. These results will be retained for a minimum of 2 years." 3. Review of the laboratory's Change of Ownership forms revealed the laboratory obtained a Certificate of Compliance on July 13, 2020. 4. In interview on 12:54 pm, Testing Personnel 1 stated the Abbott service representative had to fix the CBC instrument in August 2020 and performed calibration. Testing Personnel 1 further stated she was unable to get documentation of the calibration from the service representative. III. Based on record review and interview with personnel, the laboratory failed to retain quality control (QC) establishment raw data for Chemistry testing for at least two (2) years. Findings: 1. 1. Review of the laboratory's policies revealed the following: a) "Retention of Laboratory Records and Materials: The laboratory maintains all reports and records in accordance with the regulatory standards of CLIA and JCAHO, All Quality Control and Calibration records and worksheets., Quality Assurance and Safety records/documentation , are kept on hand for 2 years." 2. Review of the laboratory's Change of Ownership forms revealed the laboratory obtained a Certificate of Compliance on July 13, 2020. 3. Review of the laboratory's QC records for the BioRad MultiQual controls revealed the laboratory did not have documentation of the raw data used to establish the QC means and ranges for the current lot in use : a) MultiQual: Level 1 Lot 56641, Level 3 : Lot 56643 4. In interview on March 26, 2021 at 2:23 pm, Testing Personnel 1 confirmed the laboratory did not have the QC establishment documentation for the Chemistry controls. Testing Personnel 1 stated the current lot number of MultiQual was put into use in February 2020.
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: I. Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to establish complete written policies for Complete Blood Counts (CBC) flags. Findings: 1. In interview on March 26, 2021 at 10:02 am, Testing Personnel 1 stated for CBC instrument flags the samples are rerun and if flag persists the results are rejected and sent to main laboratory for a manual differential. 2. In further interview on March 26, 2021 at 12:47 pm, Testing Personnel 1 stated past results for CBC patients are reviewed. 3. Review of the laboratory's "Abbott Cell-Dyn Ruby: Complete Blood Count with a 5-Part Differential" procedure revealed the laboratory did not include detailed written instructions for handling of flagged CBC samples referred to the main laboratory. To include, but not limited do, rejection of results and review of past results. II. Based on review of the laboratory's quality control (QC) policy, manufacturer's instructions, QC records, and interview with personnel, the laboratory failed to establish their own QC ranges for Complete Blood Counts (CBC) per laboratory policy. Findings: 1. Review of the laboratory's "Abbott Cell-Dyn Ruby: Complete Blood Count with a 5-Part Differential" procedure under "Quality Control" section revealed "According to the manufacturer, each laboratory

	must establish its own ranges. These ranges are determined by evaluating data from at least a three month period for each level of control. (Data analysis from the inter-laboratory Cell-Dyn Eqc is also used.)" 2. Review of the manufacturer's instructions revealed "The recovery ranges are intended to reflect inter-laboratory and inter-instrument variability; thus are wider than the +/- 2 SD QC range for one instrument. Always perform quality control according to good laboratory practice, laboratory director's requirements. and any regulatory or acceditational requirements." 3. Review of the laboratory's CBC quality control records for the current lot (L1025, N1025, and H1025) of Cell-Dyn 26 Plus Controls revealed the laboratory did not have documentation of establishing their own QC ranges. 4. In interview on March 26, 2021 at 12:54 pm, Testing Personnel 1 stated the laboratory establishes their own QC mean for CBC and uses the manufacturer's limits. Testing Personnel 1 confirmed the laboratory does not establish their own range for CBC quality control material.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature and humidity logs and interview with personnel, the laboratory failed to perform corrective actions when the laboratory's humidity was not maintained between 30 % to 80 % for ten (10) of ninety (90) days reviewed. Findings: 1. Review of the laboratory's temperature and humidity logs for January 2021 through March 2021 revealed the laboratory did not have corrective actions for humidity that was not within acceptable range (30 % - 80 %) for the following ten (10) days: a) January 11, 2021 documented humidity 29% b) January 12, 2021 documented humidity 28% c) January 13, 2021 documented humidity 29% d) January 18, 2021 documented humidity 27% e) January 19, 2021 documented humidity 28% f) February 1, 2021 documented humidity 26% g) February 2, 2021 documented humidity 29% h) February 3, 2021 documented humidity 28% i) February 18, 2021 documented humidity 25% j) February 19, 2021 documented humidity 26% 2. In interview on March 26, 2021 at 12:47 pm, Testing Personnel 1 confirmed the identified days did not have corrective action performed for humidity values that were outside of acceptable limits.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to establish complete written policies for Complete Blood Counts (CBC) flags. Refer to D5401 I. 2. The laboratory failed to establish their own QC ranges for Complete Blood Counts (CBC) per laboratory policy. Refer to D5401 II. 3. The laboratory failed to perform corrective actions when the laboratory's humidity was not maintained between 30 % to 80 % for ten (10) of ninety (90) days reviewed. Refer to D5781
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall direction and management to the laboratory. Refer to D3031 I, D3031 II, and D3031 III.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
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 policies occurred. Refer to D5781.
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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401 I and D5401 II.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of quality control records and interview with personnel, the Technical Consultant failed to ensure the establishment of quality control means and ranges were acceptable prior to use. Findings: 1. Review of the laboratory's quality control records for the current lot of BioRad Immunoassay control Lot 85230 revealed the laboratory maintained raw data used to establish the means; however, the Technical Consultant did not review to ensure acceptability prior to use. 2. In interview on March 26, 2021 at 2:07 pm, the Laboratory Director (also serves as the Technical Consultant) stated she did not review the quality control establishment raw data prior to it being put into use. 3. In interview on March 26, 2021 at 2:07 pm, Testing Personnel 1 stated the laboratory put the identified BioRad control into use on March 5, 2021.