Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463125	08/19/2024
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 Recertification survey was performed at Laboratory Corporation of America Holdings, CLIA ID 19D0463125, on August 19, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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, manufacturer's instrument manual, quality control records, test menu, and interview with personnel, the laboratory failed

	to include written procedures for corrective actions related instrument sampling error flags for the Abbott Cell Dyn Ruby. Findings: 1. Review of the laboratory's test menu revealed the laboratory utilizes the Abbott Cell Dyn Ruby with low, normal, and high Cell Dyn 26 Plus quality control material for Complete Blood Count (CBC) testing. 2. Review of the laboratory's CBC quality control records from January 2023, August 2023, and July 2024 revealed on August 1, 2023 the normal level control had an "*" next to all CBC and automatic differential parameters. 3. Further review of the laboratory CBC QC for August 2023 revealed the laboratory had the following written note "sampling error for 8-1-23 and 9-6-23 runs within manufacturers ranges." The Testing Personnel reviewed/signed the QC on "9-6-2023" and the Laboratory Director on "9-29-23." 4. Review of the manufacturer's instrument manual revealed the following causes and corrective action for sampling error messages: a) "Probable Cause(s): "The sensor did not detect a sufficient amount of sample at the expected time following aspiration." b) "Corrective Action(s): "1. Check the specimen tube to be sure it contains a sufficient quantity of sample. Verify that the specimen contains no clots. 2. Clean the Open Mode Probe or the Closed Mode Needle as directed in Section 9: Service and Maintenance, Subsection: 6052-Clean or Replace Open Mode Probe or 6053-Clean or Replace Closed Mode Needle to remove any obstructions. 3. Clean the Shear Valve as directed in Section 9: Service and Maintenance, Subsection: 6006-Clean Shear Valve. 4. If unable to resolve this problem, contact Abbott Customer Service." 5. Review of the laboratory's "Abbott Cell Dyn for CBC with auto diff" procedure revealed the laboratory did not include corrective actions for sampling errors, to include, but not limited to retesting. 6. In interview on August 19, 2024 at 2: 30 pm, Testing Personnel 1 stated she did not repeat the identified control that had an "*" next to all CBC and automatic differential parameters since the QC values were within the acceptable limits. Testing Personnel 1 stated had a sampling error occurred on patients she would have retested the sample. Testing Personnel 1 confirmed the laboratory did not have written procedures related to corrective actions for sampling errors on the Cell Dyn Ruby.
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 procedures for assessing personnel competency were maintained for two (2) of two (2) Testing Personnel reviewed. Refer to D6046.
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 that an approved procedure manual was available to all personnel. Refer to D5403.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form, test menu, personnel competency assessment records, corrective action records, and interview with personnel, the laboratory failed to maintain documentation of 2023 competency assessment records for urine sediment microscopic examination and/or Complete Blood Count (CBC) test performance for two (2) of two (2) Testing Personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the laboratory has two (2) Testing Personnel. 2. Review of the laboratory's test menu revealed the laboratory performs CBC and urine sediment microscopic testing. 3. Review of the laboratory's 2023 Testing Personnel competency assessment records revealed the laboratory did not have documentation of an annual performance for the following tests: Testing Personnel 1: Urine sediment microscopic examination Testing Personnel 2: CBC performed on the Abbott Cell Dyn Ruby analyzer 4. Review of the laboratory's "Memorandum for Record" revealed the following: "During an internal audit, it was discovered that documentation was missing. Attempts have been made to locate missing material and/or resolve through attestation. Corrective action and/or plan of action have been adopted to prevent further recurrences. Testing Personnel 1 and 2 urine microscopic and Ruby annual competencies was {sic} due July/2023. Testing Personnel 1 and 2 urine microscopic and ruby competencies were completed August/2023. All competency due dates will be placed on the technical calendar and all competency forms will have the tests pre-filled so that no tests will be missed. Also, all competencies will be checked against previous competency and all tests that are performed at that location. There will be blank competency assessment forms left at each site. " The Laboratory Director signed document on "7-1-24." 5. Further review of the laboratory's personnel records revealed the laboratory did not have documentation of the August 2023 urine microscopic competency assessment for Testing Personnel 1 and CBC competency assessment for Testing Personnel 2. 6. In interview on August 19, 2024 at 2:35 pm, the Laboratory Director stated she could not find the identified 2023 competency assessments for Testing Personnel 1 and Testing Personnel 2.