Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	19D0462635	04/19/2023
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 Certification survey was performed on April 19,2023 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.
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 and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following: a) Written quality control procedure for blood culture bottles that included visual inspections b) Complete Blood Count (CBC) instrument flag policy, to include, but not limited to, criteria for blood smear examination and manual differentials 2. In interview on April 19, 2023 at 3:01 pm, Technical Consultant 1 confirmed the laboratory's policies did not include the identified information.
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, laboratory information system (LIS), and interview with personnel, the laboratory failed to define reporting codes in their procedure manual for urinalysis testing. Findings: 1. Review of the laboratory's "Microscopic Examination of Urine" policy under the "Reporting Microscopic Examination" section revealed the laboratory listed "record as a range;" however, the ranges/codes used by the laboratory were not defined in the policy for the following substances: leukocytes, erythrocytes, epithelial cells (non-renal), and epithelial cells (renal). 2. Further review of the laboratory's "Microscopic Examination of Urine" policy under the "Reporting Microscopic Examination" section revealed the laboratory listed "Report Present (PRESP) of Delete/autodelete (! or NOSEE)" for cast, crystals, mucus threads, yeast, and Trichomonas. 3. Review of the laboratory's LIS codes for urinalysis testing revealed the following codes are utilized: Epithelial cells: 0 ~ 0-1 2 ~ 2-3 3 ~ 3-5 5 ~ 5-10 10 ~ 10-20 20 ~ 20-50 50 ~ 50-100 > ~ >100 N ~ None Seen Erythrocytes/Leukocytes: 0 ~ 0-1 1 ~ 1-5 5 ~ 5-10 10 ~ 10-20 20 ~ 20-50 50 ~ 50-100 > ~ >100 N ~ None Seen 4. In interview on April 19, 2023 at 2:55 pm, Technical Consultant 2 stated the absence/presence of all urine microscopic findings are reported. Technical Consultant 2 further stated if a substance is not seen in the sample a code is entered; it is not deleted from the test as stated in the policy. Technical Consultant 2 confirmed the urinalysis codes utilized in the laboratory's LIS did not match the policy.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's package insert, policies, quality control (QC) records, test menu, and interview with personnel, the laboratory failed to establish their own means and ranges for QC material utilized for Urinalysis testing. Findings: 1. Observation by surveyor during the laboratory tour on April 19, 2023 at 9:08 am revealed the laboratory performs microscopic urinalysis utilizing Bio-Rad qUAntify Plus controls. 2. Review of the "Bio-Rad qUAntify Plus Levels 1 and 2" package insert under the "Assignment of Values" section revealed "Each laboratory should use the results provided only as a reference and establish its own parametes of precision." 3. Review of the laboratory's "Microscopic Examination of Urine" policy under the "Quality Control" section revealed "Control material consists of commercial urine materials, one normal and one abnormal level. (Refer to the Quality Control Manual for names of current controls and established acceptable ranges)." 4. Review of the laboratory's quality control records revealed the laboratory did not have documentation of establishing their own QC means and ranges for the Bio-Rad qUAntify Plus Control lot 79850. 5. In interview on April 19, 2023 at 11:01 am, Technical Consultant 1 stated the laboratory does not establish their own QC ranges for the urinalysis controls; they use the manufacturer's ranges. 6. Review of the laboratory's test menu revealed the laboratory performs 300 microscopic urinalysis tests annually.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. 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 that a complete quality control program was established to assure the quality of laboratory testing. Refer to D5469.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's personnel records and interview with personnel, the Laboratory Director failed to ensure one (1) of five (5) Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of personnel records for Testing Personnel 3, hired September 20, 2021, revealed the Laboratory Director did not sign off on the initial Sysmex XS training documents approving her for patient testing. 2. In interview on April 19, 2023 at 10:14 am, Technical Consultant 1 said she signed the training document for Testing Personnel 3, not the Laboratory Director.
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. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to define reporting codes in their procedure manual for urinalysis testing. Refer to D5403.