

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2208473	(X3) Date Survey Completed 09/28/2021
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 5131 O'Donovan Drive, Ste 100, 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 on September 28, 2021 at Laboratory Corporation of America, CLIA ID # 19D2208473. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policies and procedures revealed the</p>

laboratory did not have written policies and procedures that included the following: a) Quality control to include, but not limited to: the establishment and/or verification of means and ranges for new lots of Hematology and Urinalysis quality control materials b) Performance specification: detailed procedures for performing complete precision to include operator variance 2. In interview on September 28, 201 at 3:00 pm, the Technical Consultant confirmed the laboratory did not include the identified policies and procedures in their manual.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

I. Based on observation by surveyor, review of the validation studies, and interview with personnel, the laboratory failed to perform complete precision studies for Hematology testing. Findings: 1. Observation by surveyor on September 28, 2021 at 1:11 pm during the laboratory tour revealed the laboratory utilizes the Sysmex XS-1000i analyzer for Complete Blood Count (CBC) Hematology testing. 2. Review of the laboratory's validation study records for the Sysmex XS-1000i Hematology analyzer revealed the laboratory did have accuracy, precision (day to day, run to run, and within run), reportable range and reference range studies; however, the laboratory did not include documentation for complete precision studies to show operator variance. 3. In interview on September 28, 2021 at 3:00 pm, the Technical Consultant stated that Testing Personnel did participate along with the field service representative during the installation of the Sysmex XS-1000i Hematology analyzer but did not retain any documentation to show operator variance. The Technical Consultant confirmed the laboratory did not show operator variance for complete precision studies. 4. Review of the laboratory's test menu revealed the laboratory performs 1,800 CBC tests annually. II. Based on observation by surveyor, review of validation studies, and interview with personnel, the laboratory failed to perform complete precision studies for Chemistry testing. Findings: 1. Observation by surveyor on September 28, 2021 at 1:11 pm during the laboratory tour revealed the laboratory utilizes the Ortho Clinical Diagnostics Vitros 350 Chemistry analyzer for the following tests: Glucose (Gluc), Blood Urea Nitrogen (BUN), Creatinine (Crea), Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (CO₂), Total Protein (TP), Albumin (Alb), Total Bilirubin (TBil), Alkaline Phosphatase (ALP), Aspartate Transaminase (AST), Alanine Transaminase (ALT), Phosphorus (Phos), and Uric Acid (UA) 2. Review of the laboratory's validation study records for the Ortho Vitros 350 Chemistry analyzer revealed the laboratory did have accuracy, precision (day to day, run to run, and within run), reportable range and reference range studies; however, the laboratory did not include documentation for complete precision studies to show operator variance. 3. In interview on September 28, 2021 at 3:00 pm, the Technical Consultant stated that Testing Personnel did participate during the validation studies of the Ortho Vitros 350 Chemistry analyzer but did not retain any documentation to show operator variance. The Technical Consultant confirmed the laboratory did not

show operator variance for complete precision studies. 4. Review of the laboratory's test menu revealed the laboratory performs the following tests annually: Glucose - 1,776 BUN - 1,776 Creatinine - 1,776 Na - 1,776 K - 1,776 CL - 1,776 CO2 - 1,776 TP - 96 ALB - 1,776 TBil - 96 ALP - 96 AST - 96 ALT - 96 PHOS - 1,778 UA - 24

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

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 performance verification studies were complete. Refer to D5421.

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 D5403.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.