

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0974783	(X3) Date Survey Completed 03/26/2021
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 1901 Medi Park # 2062, Amarillo, TX	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Review of policies and procedures, manufacturers instructions for use, observations, review of patient test records and interview of facility personnel found the laboratory failed to establish and follow written policies and procedures for the collection, transportation, storage and handling, acceptability and testing of patient specimens submitted for testing at this laboratory using the Roche cobas Integra 400 chemistry analyzer. The findings included: 1. Review of the policies and procedures found no written instructions available to clients submitting specimens to this laboratory for testing specific to this location. 2. Review of manufacturers instructions for use for the following analytes tested on the Roche cobas Integra 400 found: a. UREAL - in vitro test for the quantitative determination of BUN (blood urea nitrogen) in serum/plasma Under the heading Stability in serum/plasma - 7 days at 20 - 25 degrees C, & days at 4- 8 degrees C, of 1 year at -20 degrees C. b. CO2-L - In vitro test for the quantitative determination of the bicarbonate (HCO3) concentration in serum/plasma Under the heading Stability - 7 days at 4-8 degrees C and 40 hours at 15-25 degrees C. c. BILT - In vitro test for the quantitative determination of Bilirubin in serum/plasma Under the heading Stability - 1 day at 20-25 degrees C, 7 days at 4-8 degrees C and 6 months at -20 degrees C. d. GLUC3 - In vitro test for the quantitative determination of glucose in serum/plasma. Under the heading Stability (no Hemolysis) 8 hours at 25 degrees C and 3 days at 4 degrees C. 3. Observations made during the delivery of</p>

specimens picked up from facilities on March 25, 2021 found: a. Delivery at 10:35 - Specimen bag temperature registered 20.5 degrees at 10:36 AM. Contained 1 specimen to be tested for lipid and CMP at reference laboratory b. Delivery made at 10:41 AM found found one patient specimen in the bag. Temperature of the contents of the delivery bag was measured at 19.3 degrees upon opening at 10:36 AM. Included in this bag was one serum separator tube (SST) and one EDTA tube for LCM req # 50083825845-0 (collected 3/24/2021 at 4:30 PM). Review of the requisition found orders for : Test code CHM U01309BC Amarillo, TX CHM 028142 CBC, Platelet, No differential CHM 322758 Basic Metabolic Panel (8) CHM 998085 Conjunction c. Delivery at 2:37 PM 6 specimens received in a bag with a measured temperature of 19 degrees. 2. Review of the final report for Control ID 50083825845 found: Date of collection recorded as 3/24/2021 1630 Local Date received: 03/25 /2021 Date reported: 03/25/2021 1210 ET Results for CBC, Platelet, No Differential and Basic Metabolic Panel (8) Review of patient specimens tested on March 24, 2021 found 14 of 14 specimens tested within 8 hours of collection. 3. Review of the Storage and Stability requirements as written in the online portal for Labcorp found: a. BUN - Maintain specimen at room temperature. Storage Instructions Stability 14 days at room temperature, 14 days refrigerated, 14 days frozen. b. CO2 - Maintain specimen at room temperature. Storage Instructions Stability 14 days at room temperature, 14 days refrigerated, 14 days frozen. c. Bilirubin - Maintain specimen at room temperature. Storage Instructions Stability 3 days at room temperature, 3 days refrigerated, 14 days frozen. d. Glucose - Maintain specimen at room temperature. Storage Instructions Stability 14 days at room temperature, 14 days refrigerated, 14 days frozen. 4. Interview of the Laboratory Director conducted on March 24, 2021 at 3:25 PM found the laboratory did not monitor the temperatures of the courier bags used to transport specimens to the laboratory. Couriers did not monitor the temperature of the bags and their contents prior to adding patient specimens or during the transportation of patient specimens. Interview of the laboratory director conducted on March 25, 2021 at 3:12 PM confirmed that the laboratory did not have written instructions available to clients for testing done at the Amarillo location. She confirmed that the only written instructions available to clients were included in the portal, which were not verified at the Amarillo location.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
Review of policies and procedures, patient test records and interview facility personnel found the laboratory failed to have written instructions available to the laboratory's clients for the appropriate collection, handling, transportation and storage of specimens submitted for Hematology and Chemistry testing performed at this site. Findings included: 1. Review of policies and procedures found that the laboratory did not have a written instructions available to the laboratory's clients for the appropriate collection, handling, transportation and storage of specimens using analyzers at this laboratory. 2. Interview of the laboratory director conducted on March 25, 2021 at 2: 37 PM confirmed that the laboratory had no written instructions available to clients for specimens submitted for testing at this location. She confirmed that the clients submitting specimens for testing used the criteria as written in the specimen

requirements in the online portal, but they did not reflect the manufacturers specifications for the equipment used at this laboratory.