

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2028103	(X3) Date Survey Completed 10/07/2021
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 7 Mcdowell Street, Suite 300, Asheville, NC	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory records and absence of documentation 10/7/21, the laboratory failed to retain manufacturer's QC(quality control) assay sheets for chemistry and endocrinology testing for 2 years. Findings: Review of 2019,2020, and 2021 laboratory QC records for the Roche Cobas Integra 400 and the Roche Cobas e411 revealed the laboratory failed to retain the BioRad Liquichek Immunoassay Plus Control assay sheets and the BioRad Liquichek Unassayed Chemistry Control assay sheets for the following lot numbers: 1. Liquichek Immunoassay Plus Control level 1 lot# 40971 and level 3 lot # 40973, expiration date: 6/30/20; 2. Liquichek Immunoassay Plus Control level 1 lot# 40991 and level 3 lot # 40993, expiration date: 12/31/20; 3. Liquichek Unassayed Chemistry Control level 1 lot # 56921 and level 2 lot #56922, expiration date: 1/31/21; 4. Liquichek Unassayed Chemistry Control level 1 lot # 56961 and level 2 lot# 56962, expiration date: 3/31/22.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p>

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, observation, and interview with the GS(General Supervisor) 10/7/21, the laboratory failed to follow manufacturer's instructions for storage of control material used on the Roche Cobas e411 for Estradiol testing. Findings: The BIORAD Liquichek Immunoassay Plus Control Level 1, 2, and 3 product insert state, "...STORAGE AND STABILITY...Once thawed, opened, and stored tightly capped at 2 to 8 degrees C(Celsius), this product will be stable as follows: All analytes: 14 days Except : Estradiol: 5 days..." During tour of the laboratory at approximately 4:20 p.m, the surveyor observed one open bottle of level 1 and one open bottle of level 3 BIORAD Liquichek Immunoassay Plus control, available for use. Both bottles were labeled with open date of 10/4/21 and expiration date of 10/18/21. At approximately 4:45 p.m., the GS confirmed the laboratory is using the BIORAD Liquichek Immunoassay Plus control for 14 days.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on review of laboratory's procedures, review of the manufacturer's instructions, and review of maintenance records 10/7/21, the laboratory failed to perform and document maintenance procedures for the Roche Cobas Integra 400 analyzer at the frequency required by the manufacturer. Findings: The laboratory's "Quality Control Outline" procedure states, "II. Instrument Maintenance: Proper care and maintenance of the laboratory equipment is also a major component of the quality control program. Maintenance procedures, recommended by the manufacturer, are performed to ensure accuracy and precision on each instrument." The Cobas Integra 400 user manual states, "Replace electrode...You must replace electrodes when their expiration date is exceeded or when the ISE results deteriorate despite regular service..." The Cobas Integra 400 analyzer "Daily check list, maintenance log and General procedures" show a frequency of 30 days for Chloride electrode replacement and 180 days for Sodium and potassium electrode replacement. Review of Cobas Integra 400 maintenance records revealed the laboratory failed to replace the chloride and potassium electrodes at the frequency required for the following: a. Chloride electrode was replaced on 11/18/19; was due on 12/18/19, and not replaced again until 1/20/20; b. Chloride electrode was replaced on 4/20/20; was due on 5/20/20, and not replaced again until 6/16/20; c. Potassium electrode was replaced on 10/18/19; was due on 4/18/20, and not replaced again until 9/24/20.