

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2139237	<b>(X3) Date Survey Completed</b>  08/21/2019
<b>Name of Provider or Supplier</b>  Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b>  800 St Vincent'S Drive Suite 500, Birmingham, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the BHCG (Beta Human Chorionic Gonadotropin) calibration verification (C-V) records and an interview with the Laboratory Supervisor, the laboratory failed to ensure the calibrator verification kit was used before its expiration date. This was observed on one of three 2018-2019 C-V's reviewed. The findings include: 1. A review of records for the Tosoh AIA-900 analyzer revealed calibrations of BHCG utilize a two-point calibration curve. Analytes calibrated with less than three calibrators require semi-annual calibration verification studies. 2. A review of the BHCG C-V records revealed the laboratory verified their calibration on 2/27/2019 using samples from the Audit Microcontrols kit Lot number 06696. However, a review of the manufacturer's package insert revealed the kit expired on 2/24/2019. 3. During an interview on 8/21/2019 at 12:55 PM, the Laboratory Supervisor reviewed the C-V records with the testing personnel, and confirmed the above noted findings. SURVEYOR ID #32558 Licensure and Certification Surveyor</p>