

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2137534	<b>(X3) Date Survey Completed</b> 06/21/2021
<b>Name of Provider or Supplier</b> Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b> 205 Hospital Drive Suite Q, Mc Kenzie, TN	
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>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, the laboratory's proficiency testing records, patient number six test report and interview with the laboratory supervisor, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) procedures twice a year in 2020 and 2021. The findings include: 1. Review of the laboratory procedure manual revealed the laboratory performs testing for KOH. 2. Review of the laboratory's proficiency testing records for 2020 and 2021 revealed no participation in proficiency testing for KOH and no other records available that verified the accuracy of the KOH test. 3. Review of patient number six test report dated 03.06.2021 revealed testing for KOH. 4. Interview with the laboratory supervisor on June 21, 2021 at 2pm confirmed the laboratory failed to verify the accuracy of the KOH procedure twice a year in 2020 and 2021 with patient testing performed.</p>
<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>

This STANDARD is not met as evidenced by:  
Based on observation of the phlebotomy area and interview with the laboratory supervisor, the collection tube used for performing stat chemistry tests was expired. The findings include: 1. Observation of the phlebotomy area on June 21, 2021 at 8:30 am revealed the lithium heparin tubes used for performing chemistry tests expired on 04.30.2021. 2. Interview with the laboratory supervisor on June 21, 2021 at 2pm confirmed the Lithium Heparin stat chemistry tubes expired on 04.30.2021. The tubes were in use for collecting patient samples for chemistry tests.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of patient test report and interview with the laboratory supervisor, the final patient test report failed to include specimen source for Potassium Hydroxide (KOH) in 2021. The findings include: 1. Review of patient number six final test report for KOH, dated 03.06.2021 revealed no specimen source and/or site. 2. Interview with the laboratory supervisor on June 21, 2021 at 2pm confirmed that the source/site was not included on the final KOH patient test report.