

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2040019	(X3) Date Survey Completed 07/10/2019
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 214 East Elm Street, Graham, 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
D5417	<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 observation and interview with TP (testing personnel) on 7/10/2019, the laboratory failed to discard a mononucleosis(Mono) test kit that had exceeded its expiration date. Findings: During tour of the laboratory at approximately 12:30 pm, the surveyor observed an expired Monolex system kit (lot #229841, expiration date: 5 /14/19) stored in the refrigerator, that was available for use. During interview at approximately 12:35 pm, TP #1 confirmed the Monolex kit was expired. She stated Mono testing is not performed very often.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's 2018 and 2019 temperature and humidity logs, review of corrective action logs, and interview with TP (testing personnel) 7/10/19, the laboratory failed to ensure corrective action was taken and documented for humidity readings outside the acceptable limits and failed to ensure corrective actions taken corrected the problem. Findings: Instructions on the laboratory's temperature</p>

and humidity logs state "***If temp or humidity is out of range, circle and indicate corrective action on log". 1. Review of 2018 and 2019 temperature and humidity logs revealed room humidity was outside the acceptable limits of 35-55% on the following days with no corrective action documented: a. 9 of 21 days in April 2018 - 4/2, 4/5, 4/6, 4/9, 4/10, 4/11, 4/12, 4/13, 4/30; b. 1 of 22 days in April 2019 - 4/8; c. 7 of 22 days in May 2019 - 5/2, 5/8, 5/15, 5/17, 5/29, 5/30, 5/31. During interview at approximately 12:45 p.m., TP #1 stated the out of range humidity readings must have been overlooked because they were not circled on the log. 2. Review of 2018 and 2019 corrective action logs revealed corrective action taken for room humidity outside the acceptable limits of 35-55% on the following days failed to correct the problem: a. November 2018 - 11/21, 11/23, 11/27, 11/28, 11/29. Readings documented after corrective action was taken were still outside acceptable limits, but there was no documentation to indicate that any additional corrective action was taken.