

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2068467	(X3) Date Survey Completed 06/20/2018
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 1710 Kernersville Medical Parkway Suite 116, Kernersville, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the general supervisor 6/20/18, the laboratory's procedure manual was not complete and current for the testing performed. Review of the laboratory's procedure manual revealed a "Workflow Procedure" (revised 7/30/14) which states on page 2 "REQUISITIONS A. Specimens ... 1. Laboratory orders and patient demographics will be printed from EPIC Electronic Medical Records and information will be interfaced utilizing ... test numbers into Cerner. ... " On page 3, it states "... B. Verification Procedure for</p>

Reporting After the instrument results are obtained, the test results will either be manually entered or results will be electronically interfaced into the Cerner LIS. ..."
Review of the laboratory's procedure manual also revealed a "Daily Results Entry Review" procedure (revised 7/18/14) which states on page 1 " ... PROCEDURE ... 2. Tech results manual and/or interfaced results in Cerner (LIS system). ..." During interview at approximately 2:25 p.m., the general supervisor stated that results are entered directly into EPIC. She stated the procedures had not been updated to reflect the laboratory's current method for reporting patient test results.