

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0993524	<b>(X3) Date Survey Completed</b>  03/19/2018
<b>Name of Provider or Supplier</b>  Laboratory Corporation Of America-Earth City, Mo	<b>Street Address, City, State</b>  13665 Lakefront Drive Ste B, Earth City, MO	
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>D5403</b>	<p><b>PROCEDURE MANUAL</b> 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 review of the hematology procedure manual revealed and interview with the technical supervisor on March 19, 2018 at 4:00 p.m. confirmed, the procedure manual failed to include normal values for manual white blood cell differentials.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed</p>

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.

This STANDARD is not met as evidenced by:  
Based on review of the manufacturer's instructions, laboratory's humidity log and interview with the technical supervisor, the laboratory failed to follow the manufacturer's instructions and the laboratory's stated performance specifications for 11 of 11 testing days from March 9, 2018 to March 19, 2018. Findings: 1. The manufacturer's instructions for the CA500 coagulation analyzer states, "Use it at a relative humidity range of 30 - 85%." 2. Review of the humidity log shows the laboratory's acceptable humidity range specification is 30 - 80%. The laboratory documented a minimum and maximum humidity value each day. 3. Review of the humidity log showed 17 of the 22 documented humidity values from March 9, 2018 to March 19, 2018 were lower than the manufacturer's instructions and the laboratory's limits. 4. Interview with the technical supervisor on March 19, 2018 at 4:00 PM confirmed the laboratory failed to follow the manufacturer's instructions and the laboratory's specifications for humidity requirements. Based on review of manufacturer's instructions for phosphate buffered saline (PBS) for dilution of semen analysis, lack of documentation for pH and interview with the technical supervisor, the laboratory failed to follow manufacturer's instructions for PBS preparation. Findings: 1. PBS manufacturer's instructions for dilution of semen analysis states "Reconstituted buffer should have a pH of 7.4 +/- 0.2." 2. No documentation was provided to show PBS pH was monitored. 3. Interview with technical supervisor on March 19, 2018 at 4:00 PM confirmed, the laboratory failed to monitor the pH of the PBS per manufacturer's instructions.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:  
Based on observation of ISE cleaning solution for the Cobas e411 and NERL reagent grade water for the Sysmex CA 500 and interview with the technical supervisor, the laboratory failed to use unexpired reagents. Findings: 1. Observation of two bottles of ISE cleaning solution (lot # 121 595-01) for Cobas e411 chemistry immunoassay testing showed an expiration date of 9/2017. 2. Observation of one box of NERL reagent grade water opened 1/12/2018 (lot # 977147) for Sysmex CA 500 coagulation testing showed 30 days opened stability. 3. Interview with the technical supervisor on March 19, 2018 at 1:30 p.m., confirmed the laboratory used reagents past their expiration date.

**D5781**

CORRECTIVE ACTIONS  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the humidity log and interview with the technical supervisor, the laboratory failed to document corrective actions taken for unacceptable humidity readings for seven of seven days from March 13, 2018 to March 19, 2018. Findings: 1. Review of the humidity log showed the laboratory failed to document corrective action taken for seven days from March 13, 2018 to March 19, 2018 for the humidity readings that fell outside of the 30 - 80% range. 2. Interview with the technical supervisor on March 19, 2018 at 3:00 PM confirmed the laboratory failed to document corrective action taken on unacceptable testing humidity conditions.