

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0447574	<b>(X3) Date Survey Completed</b>  06/27/2018
<b>Name of Provider or Supplier</b>  Cox Medical Center North	<b>Street Address, City, State</b>  1423 North Jefferson, Springfield, 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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the coagulation procedure manual, coagulation/prothrombin time records for 2017 and to date June 27, 2018 and interview with technical supervisor #6, the laboratory failed to follow procedures for validating reference intervals (normal values) before each lot number of Innovin reagent is put into service for patient testing. Findings: 1. The coagulation procedure manual revised August 28, 2017 states, "reference interval values are validated before each Innovin lot number is put into service." 2. Review of prothrombin time coagulation records revealed no documentation to show the laboratory validated reference intervals for Innovin reagent lot number 539393 in service from April 2017 through April 19, 2018. No documentation was available to show the laboratory validated reference intervals for Innovin lot number 549717 in service after April 19, 2018 and to date June 27, 2018. 3. Interview with technical supervisor #6 on June 27, 2018 at 12:30 PM confirmed, the laboratory failed to follow the coagulation procedure for validating reference intervals for each lot number of Innovin reagent before reporting patient results.</p>
<b>D5403</b>	<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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of hematology/manual differential procedures revised May 11,2017 and in use, and interview with technical supervisor # 9 on June 27, 2018 at 12:30 PM confirmed, the procedure manual failed to include normal values for cells evaluated /counted on manual differential procedures.

**D5413**

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, lack of humidity records documentation for 2017 and to date 2018, and interview with technical supervisor #3 , the laboratory failed to define criteria for humidity conditions consistent with the manufacturer's instructions (specifications). Findings: 1. Review of manufacturer's specifications for operation of the Sysmex XN-1000 hematology analyzers showed acceptable humidity limits of 30 to 95 percent. 2. Review of manufacturer's specifications for operation of the Dimension EXL chemistry analyzers showed acceptable humidity limits of 30 to 85 percent. 3. Interview with technical supervisor # 3 on June 27, 2018 at 12:30 PM revealed the Sysmex hematology analyzers were placed in service for patient testing March 2017 and currently in use. The Dimension EXL analyzers were placed in service for patient testing July 2015 and currently in use. Interview confirmed the laboratory failed to define, monitor and document humidity conditions consistent with manufacturer's specifications for all instruments.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of Glocyte automated cell counter system for CSF procedure, observation of 30ul and 10ul MLA pipettes and interview with the technical supervisor #6, the laboratory failed to annually calibrate the pipettes in 2018.

Findings: 1. Review of the Glocyte automated cell counter system for CSF procedure states "Annually return the fixed volume pipettes (10 and 30 ul) to Advanced instruments for routine calibration." 2. Observation of 10ul pipette showed calibration was due 3/18. 3. Observation of 30ul pipette showed no documentation to show when calibration was due. 4. Interview with the technical supervisor #6 on June 27, 2018 at 11:30 AM confirmed the laboratory failed to annually calibrate the pipettes.

**D5807**

**TEST REPORT**

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient hematology test reports, hematology procedure manuals and interview with technical supervisor # 9, the laboratory failed to ensure pertinent patient normal were available for interpretation. Two of two selected test reports revealed different normal values from those stated in the approved procedure manual.

Findings: 1. The differences between normal values on two patient test reports reported March 5, 2018 and those included in the procedure manual revised May, 11, 2017 and currently in use are as follows: Normal values included on male patient test report reported March 5, 2018: red blood cells (RBCs) 4.50-6.00 million/mm<sup>3</sup> MCH 26.0-34.0 pg MCHC 31.0-36.5 g/dl RDW 11.5-16.0 % Normal values included on female patient test report reported March 5, 2018: RBCs 4.00-5.20 million/mm<sup>3</sup> MCH 26.0-34.0 pg MCHC 31.0-36.5 g/dl RDW 11.5-16.0 % Normal values included in the hematology procedure manual: RBCs male 4.6-6.2 million/mm<sup>3</sup> RBCs female 4.2-5.4 million/mm<sup>3</sup> MCH (male/female) 27-33 pg MCHC (male/female) 32-36 g/dl RDW (male/female) 11.5-14.5% 2. Interview with technical supervisor # 9 on June 26, 2018 at 12:30 PM confirmed the normal values stated in the approved hematology procedure manual differed from those included on patient test reports.