

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0446842	<b>(X3) Date Survey Completed</b>  05/22/2018
<b>Name of Provider or Supplier</b>  Mercy Clinic Laboratory Services Rolla	<b>Street Address, City, State</b>  1605 Martin Springs Dr, Ste 110b, Rolla, 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>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 review of the coagulation and hematology procedure manual, and interview with the director of laboratory operations, the procedure manuals failed to include reference intervals (normal values) for prothrombin time/INR testing and immature granulocytes / bands performed by manual differential procedure. Findings: 1. The coagulation procedure manual did not include normal values for prothrombin time /INR testing. 2. The hematology procedure manual did not include normal values for immature granulocytes/ bands performed by manual differential procedure. 3. Interview with the director of laboratory operations on May 22, 2018 at 11:00 AM</p>

confirmed the manuals did not include normal values, approved by the laboratory director, for prothrombin time/ INR testing and immature granulocytes/bands performed by manual differential.

**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, daily humidity records documentation for 2018, laboratory policy and interview with the director of laboratory operations, the laboratory failed to define criteria for humidity conditions consistent with the manufacturer's instructions (specifications). The humidity conditions failed to meet manufacturer's specifications for 21 of 22 testing days in January, 14 of 19 testing days in February, 17 of 22 testing days in March and 12 of 21 testing days in April 2018. Findings: 1. Review of manufacturer's specifications for operation of the STA Satellite coagulation analyzer showed acceptable humidity limits of 20 to 80 percent. 2. Review of manufacturer's specifications for operation of the Cobas 6000 series chemistry analyzer showed acceptable humidity limits of 30 to 85 percent. 3. Review of manufacturer's specifications for operation of the Sysmex XS 1000i hematology analyzer showed acceptable humidity limits of 30 to 85 percent. 4. Review of daily humidity records documentation showed laboratory humidity conditions did not reach the manufacturer's minimal/ low limit requirements for 21 testing days in January, 14 testing days in February, 17 testing days in March and 12 testing days in April 2018. The daily humidity records (log sheet) showed the laboratory defined humidity criteria as 90 percent maximum. 5. Review of procedure "Refrigerator/Freezer Maintenance and Temperature Control" states, "For humidity, you must take all the instrumentation specifications and create a range that is within the specifications for all instruments. If the humidity is out of range ensure that a humidifier is available during the dry season. 6. Interview with the director of laboratory operations on May 22, 2018 at 09:00 AM confirmed, the laboratory failed to create a humidity range within the manufacturer's specifications for all instruments and ensure that a humidifier is available during the dry season as stated in the policy.