

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0450938	<b>(X3) Date Survey Completed</b>  01/11/2019
<b>Name of Provider or Supplier</b>  Caldwell Regional Medical Center	<b>Street Address, City, State</b>  761 West 175th Street South, Caldwell, KS	
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 blood bank procedure, manual differential procedure, lab personnel qualifications and interview with the general supervisor the laboratory failed to have blood bank procedure to check for patient history pertinent to the laboratory and the laboratory failed to differentiate manual differential testing between moderate and high complexity testing personnel. Findings: 1. Review of blood bank procedure "blood bank back up policy" states "check file cabinet for previous typing and place at the Blood Bank workstation." Interview with the general supervisor revealed the testing personnel check the file cabinet and the computer for</p>

patient history before starting crossmatch. 2. Review of manual differential procedure "Criteria for manual differential" states "if bands, atypical lymphs, immature or other abnormal cells are noted, perform manual differential." Interview with general supervisor revealed testing personnel #3 and #4 are qualified for moderate complex testing. Moderate complexity testing for manual differentials cannot include immature cells. 3. Interview with the general supervisor on January 11, 2019 at 12:30 PM confirmed the laboratory failed to have a pertinent blood bank procedure to check for patient history and failed to differentiate manual differential testing between moderate and high complexity testing personnel.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of Siemens Dimension EXL 200 chemistry validation and interview with the general supervisor on January 11, 2019 at 12:30 PM confirmed the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel #1 competency for blood bank, hematology manual differentials and interview with the general supervisor on January 11, 2019 at 12:30 PM confirmed the technical supervisor #1 failed to evaluate competency for testing personnel #1 for blood bank and hematology manual differentials.