

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0453242	<b>(X3) Date Survey Completed</b>  03/08/2022
<b>Name of Provider or Supplier</b>  Minneola District Hospital	<b>Street Address, City, State</b>  212 Main Street, Minneola, 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 upon a review of the laboratory procedures and interview, the laboratory failed to define in the written procedures: Reference intervals (normal values), Analytica Measurement Range (AMR) and panic values for the ACL Elite, Dimension EXL 200 and Osmetech OPTI CCA policies at time of survey. Findings: 1. The policy for the ACL Elite (Prothrombin Time (PT), Partial Thromboplastin Time (PTT), and D-Dimer) did not contain information for the reference intervals (normal values), AMR and panic values. 2. The policy for the Dimension EXL 200 (38 chemistry analytes) did not contain information for the reference intervals (normal values), AMR and</p>

panic values. 3. The policy for the Osmetech OPTI CCA (pH, pCO<sub>2</sub>, pO<sub>2</sub>) did not contain information for the reference intervals (normal values), AMR and panic values. 2. Interview with the technical consultant (TC) on March 8, 2022 at 9:25 a.m. confirmed, the laboratory failed to define in the written procedures: Reference intervals (normal values), Analytica Measurement Range (AMR) and panic values for the ACL Elite, Dimension EXL 200 and Osmetech OPTI CCA policies at time of survey.

**D5411**

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

Test systems must be selected by the laboratory. The testing must be performed 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 a review of manufacturer's instructions, temperature monitoring records and interview, the laboratory failed to ensure that chemistry controls (immunoassay) were stored at the required temperature at time of survey. Findings: 1. A review of the manufacturer's instructions for Bio-Rad Liquichek Immunoassay Control revealed that the proper unopened storage requirement was -20 degrees Celcius(C) to -70 degrees C. 2. A review of the temperature monitoring system records from 10/01/21 to 12/31 /21 for the lab freezer showed 85 different temperatures recorded during this period failed to maintain consistent manufacturer's required temperature. The period of daily temperatures reviewed for the freezer showed 7 dates when temperature was at the acceptable range to meet the manufacturer's requirements. Temperature log sheets listed an incorrect acceptable range of -15 C to -25 C. 3. Interview with technical consultant (TC) 3/8/22 at 12:30 p.m. confirmed, the laboratory failed to ensure that chemistry controls were stored at the required manufacture temperatures at time of survey.