Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453242	01/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Minneola District Hospital	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2019 American Proficiency Institute (API) Proficiency Testing (PT) documentation, CMS-209 form and interview with Technical Consultant (TC) #1, the laboratory failed to document proficiency testing evaluation and verification activities for the specialties of immunohematology by qualified personnel for 2019. Findings: 1. Review of the laboratory's 2019 APT PT documentation for immunohematolgy lacked documentation for evaluation and verification activities by qualfied personnel. a. Two of two Immunohematology PT Performance Evaluations for 2019 include compatibility testing, which is high complexity. b. Two of two Immunohematology PT Performance Evaluations for 2019 were signed by TC #1 only. TC #1 does not meet the qualifications for Technical Supervisor in this specialty. 2. CMS-209 form lists TC #1 for immunohematology, moderate complexity. 3. Interview on January 7, 2020 at 1:00 p.m.with TC #1 confirmed, the laboratory failed to document proficiency testing evaluation and verification activities for the specialties of immunohematology by qualified personnel for 2019.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview, the laboratory failed to include reference ranges for hematology in the procedure manual. Findings: a. Review of the procedure manual for hematology did not include reference ranges for the automated complete blood count. b. Interview on January 7, 2020 at 11:30 a.m. with TC #1 confirmed, the laboratory failed to include reference ranges for hematology in the procedure manual.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 upon a review of the laboratory's personnel competency assessment records and staff interview, the laboratory failed to ensure that personnel performing patient testing were assessed for all required elements of competency. Findings: 1. Review of the laboratory's competency assessment records revealed that the laboratory did not address the following methods/elements of competency: a. Review of test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. b. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. Interview on January 7, 2020 at 10:05 a.m. with TC #1 confirmed, the laboratory failed to ensure that personnel performing patient testing were assessed for all required elements of competency.