

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0451041	(X3) Date Survey Completed 07/14/2020
Name of Provider or Supplier Kiowa County Memorial Hospital	Street Address, City, State 721 West Kansas Ave, Greensburg, 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
D5393	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c)</p> <p>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on the review of policy, lack of preanalytical assessment documents and interview, the laboratory failed to perform a review of the effectiveness of preanalytical systems quality assessment. Findings: 1. Review of the policy Quality Assessment showed the requirement of monitoring specimen quality and developing corrective action (CA) to address errors or potential problems. 2. No specimen rejection log entries were available for review at the time of survey. 3. When Testing Personnel (TP) #1 was asked how the specimen rejections were reviewed to determine if CA was needed, she stated that specimen rejection was noted only on the requisition, but no review or CA process was in place. 4. Interview of TP #1 on July 14, 2020 at 9:50 a.m. confirmed, the laboratory failed to perform a review of the effectiveness of preanalytical systems quality assessment.</p>
D5403	<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</p>

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: 1. Review of the procedure manual for hematology did not include reference ranges for: a. Complete Blood Count procedure b. Differential Leukocyte Count Peripheral Smear procedure c. CA 620 Coagulation PT, INR, aPTT procedures 2. Interview on July 15, 2020 at 3:15 p.m. with the Laboratory Director confirmed, the laboratory failed to include reference ranges for hematology in the procedure manual.