Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450954	07/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Comanche County Hospital	202 S Frisco, Coldwater, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of documentation and interview, the laboratory failed to assess the competency of Technical Consultant (TC) #3. Findings: 1. No competency documentation for TC #3 was available at the time of survey. 2. Interview with Testing Personnel (TP) #1 on July 15, 2020 at 11:55 a.m. confirmed, the laboratory failed to assess the competency of TC #3.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) 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. 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 made available for review at the time of survey. 3. Interview of TP #1 on July 15, 2020 at 10:05 a.m. confirmed, the laboratory failed to perform a review of the effectiveness of preanalytical systems quality assessment.
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 the laboratory's method verification documentation, non-waived test list, and interview, the laboratory failed to verify that the reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results. Findings: 1. Review of the method verification of the TOSOH A1A-360, Serial # 28088608 revealed the laboratory performed an instrument verification from May 8, 2019 through June 3, 2019. The laboratory started reporting patient test results on June 4, 2019. 2. The non-waived test list provided at the time of survey, listed 3 analytes as performed on the TOSOH A1A-360: PSA, FT4 and TSH. 3. No documentation for verification of the manufacturer's normal values were available for 3 of 3 analytes at the time of survey. 4. Interview with TP #1 on July 15, 2020 at 4:40 p.m. confirmed, the laboratory failed to verify that the reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on the review of procedures, documentation and interview, the laboratory failed to perform routine verification of platelet poor plasma for the centrifuge. Findings: 1. Review of the procedure "Centrifuge Calibration Verification of Platelet Poor Plasma states "Centrifuge speed and duration must be established and verified by the testing lab to ensure platelet counts are less than 10,000/uL. These parameters will be validated every six months or after repair or preventative maintenance of the centrifuge." 2. Review of the accuracy check records provided for the centrifuge showed 4/18/2019 as the only date validation was performed. No other records were made available at the time of survey. 2. Interview with the TP #1 on July 15, 2020 at

	2:05 p.m. confirmed, the laboratory failed to perform routine verification of platelet poor plasma for the centrifuge.