Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453239	04/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Meade District Hospital	510 E Carthage Street, Meade, 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
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: 1. A review of manufacturer's instructions for Rediplastin , quality control and quality assessment records for coagulation, observation of the laboratory's equipment, and interview with staff on April 23, 2019 revealed that the laboratory did not verify the performance specifications of The ACL Top 300, prior to reporting patient test results for new lot of Rediplastin . The laboratory failed to verify accuracy for 5 months out of 11 months for Prothrombin Time (PT). Findings: a. During the interview with the General Supervisor #1 on April 23, 2019 @ 1230, review of the information stored on the ACL TOP 300 instrument and records of the normal patient mean for lot N0688780 and lot# RN0278177, revealed that the patient normal mean of 11.7 sec for N0688780 was not inputted into the ACL TOP 300. Therefore the accuracy of the PT wasn't verified from November 7, 2018 to April 23, 2019. b. Quality control and quality assessment records for ACL Top 300 coagulation analyzer on April 23, 2019 did not include determination of the Prothrombin Time (PT) for patient normal range for the current lot of Rediplastin in use from November 7, 2018 to April 23, 2019. Therefore the accuracy or reliability can not be verified.