Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452429	11/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clay County Medical Center	617 Liberty Street, Clay Center, 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
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 a patient test report, non waived test list, the CA-600 coagulation analyzer procedure, and interview, the laboratory failed to have reference ranges in the procedure for all tests values reported on patients. Findings: 1. Review of a patient test report for Protime (PT) with International Normalized Ratio (INR) from October 31, 2019 included a reference range for INR as 0.91-1.16 INR. 2. KS-CLIA-PS01, non-waived test list provided at the time of survey, listed Protime as performed on the Sysmex CA-600. 2. Review of the CA-600 coagulation procedure did not include a reference range for INR, a reported value calculated from the PT result. 4. Interview

	with General Supervisor (GS)#1 on November 5, 2019 at 5:20 p.m. confirmed, the laboratory failed to have reference ranges in the procedure for all tests values reported on patients.
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 Dimension EXL with LM, Serial # DR251548 revealed the laboratory performed an instrument verification from October 4, 2018 through October 12, 2018. The laboratory started reporting patient test results on November 1, 2018. 2. The KS-CLIA-PS01, non-waived test list provided at the time of survey, listed 59 analytes as performed on the Dimension EXL with LM. 3. No documentation for verification of the manufacturer's normal values were available for 59 of 59 analytes at the time of survey. 4. Interview with GS#1 on November 5, 2019 at 5:20 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.