Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452410	04/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mitchell County Hospital Health Systems	400 W 8th St, Beloit, 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 upon a review of the laboratory procedures and interview, the laboratory failed to define by written procedure: Step-by-step performance of the procedure, control procedures, corrective action procedures, reference intervals (normal values), panic values with protocol for notification and instruction for entering results in the patient record for Prothrombin Time (PT), Partial Prothrombin Time (PTT), Fibrinogen and D-Dimer performed on the Sysmex CA coag test system. Findings: 1. The test procedure for PT, PTT, Fibrinogen and D-Dimer performed on the Sysmex CA coag test system was requested for review. What was provided were printed copies of the

	Siemen instructions for reagent use. This documents did not contain information for step-by-step performance of the procedure, control procedures, corrective action procedures, reference intervals (normal values), panic values with protocol for notification and instruction for entering results in the patient record for PT, PTT, Fibrinogen and D-Dimer. 2. Iinterview with the general supervisor (GS) #1 on April 20,2021 at 1:20 p.m. confirmed, the laboratory failed to define by written procedure: Step-by-step performance of the procedure, control procedures, corrective action procedures, reference intervals (normal values), panic values with protocol for notification and instruction for entering results in the patient record for Prothrombin Time (PT), Partial Prothrombin Time (PTT), Fibrinogen and D-Dimer performed on the Sysmex CA coag test system.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A review of manufacturer's instructions, lack of reference range verification data and interview revealed the laboratory failed to follow manufacturer's instruction on refernce intervals (normal values) for PTT.. Findings: 1. Review of the Siemens Dade Actin FSL reagent package insert for PTT under Expected Values revealed the following statement: Refence intervals vary from laboratory to laboratory depending on the population served and the technique, method, equipment and reagent lot used. Thereefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed. 2 No reference range verification or validation data for the current lot of PTT reagent in use was made available at the time of survey. 3. Interview with GS #1 on April 20, 2021 at 1: 55 p.m. confirmed, the laboratory failed to follow manufacturer's instruction on refernce intervals (normal values) for PTT.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: A review of the Chemistry QC/Corrective Action log and interview revealed the laboratory failed to evaluate patient test results since the last acceptable test run to determine if patient results have been adversely affected and may require corrective action. Findings: 1. Review of the Chemistry QC/Corrective Action log for February and April 2021 revealed: a. February 5-- Calcium QC failure, calibration performed,

	QC OK-no documentation of prior patient results evaluation noted. b. February 22--NKCl QC failure, calibration performed, QC OK-no documentation of prior patient results evaluation noted. c. February 27--ALT QC failure, calibration performed, QC OK-no documentation of prior patient results evaluation noted. d. April 4--BUN QC failure, calibration performed, QC OK-no documentation of prior patient results evaluation noted. e. April 18--D Bil QC failure, calibration performed, QC OK-no documentation of prior patient results evaluation noted. 2. When staff was asked if other monthly chemistry QC logs would show documentation of prior patient result evaluation when QC failed to meet acceptable criteria, GS#1 response was no. 3. Interview with GS #! April 20,2021 at 11:10 a.m. confirmed, the laboratory failed to evaluate patient test results since the last acceptable test run to determine if patient results have been adversely affected and may require corrective action.