Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452410	08/01/2018
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of Profile-V MedTox package insert, quality control (QC) records from January to July 2018, and interview with the Technical Consultant revealed that the laboratory failed to perform the quality control as required by the manufacturer. Findings were: 1. The package insert for the PROFILE-V MEDTOXSCAN Test states that external controls should be run routinely once per week. 2. Review of quality control records for January 2018 to July 2018 found that QC was performed: Lot: 833075-19 January 11, 2018 Lot: TD041J19 February 14, 2018 and March 16, 2018 Lot: TD070M19 April 25, 2018 and May 26, 2018 Lot: TD081K20 June 7, 2018 and July 26, 2018 3. Interview with the Technical Consultant at 11:45 AM on August 1, 2018 confirmed QC was performed monthly instead of weekly per manufacturer guidelines and that six patients were tested during July 2018.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for

	sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies/procedures, lack of quality control (QC) results during 1/1/2017 to 7/31/2018, and interview with the Technical Consultant, the laboratory failed to check each batch of bacteriology media to ensure it supported the growth, or as appropriate, selected or inhibited specific organisms to produce the intended biochemical responses. Findings were: 1. A review of the laboratory's procedure for QC of microbiology culture media and the IQCP did not include performing QC for each batch or shipment for the following microbiology media in use: Blood agar, MacConkey agar; CNA/MacConkey biplate, Tryptic Soy agar, and Spectra MRSA agar. 2. Interview with the technical consultant on 8/1/2018 at 11:00 confirmed the lab was not performing quality control on each batch of media with controlled organisms to ensure the media supported intended growth and/or the intended response.