Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0047279	07/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Phillips County Health Systems	1150 State Street, Phillipsburg, 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 inserts and both quality control (QC) and patient records from May to July 2017, and interview with the General Supervisor revealed that the laboratory failed to perform quality control required by the manufacturer. Findings were: 1. The package insert for the PROFILE-V MEDTOXSCAN Test states that external controls should be run once per week. 2. Review of quality control records for March 2018 to July 2018 found that QC was performed March 1, 2018, April 1, 2018, and May 1, 2018 for lot TA970E19 and May 2, 2018, June 1, 2018, and July 1, 2018 for lot TA011K19. 3. Review of patient records for May 2018 to July 2018 showed 6 patients tested during the weeks QC was performed with a total of 17 patients tested during the three months. 4. Interview with the General Supervisor at 11:45 AM on July 30, 2018 confirmed QC was performed monthly and not weekly per manufacturer guidelines.
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 Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with General Supervisor from the CMS 209 07 /30//2018 at 09:30 hrs. confirmed the laboratory failed to have the policy, (All patients 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).
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: A review of quality control records and interview with staff revealed the laboratory policy failed to have a method to monitor, review, and provide documentation for quality controls failures, shifts or trends. Findings were as follows: 1. Based upon interview with the General Supervisor from the CMS form 209 on 07/30/2018 at 10: 10 a.m., the laboratory failed to produce documentation of monitoring and review of quality control failures, shifts, and trends for the Cell Dyne Ruby Hematology analyzer.