Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307908	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Springfield Health Services, Llc	100 Northcrest Drive, Springfield, TN	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Intakes: TN00043369 Intakes: TN00043369 Based on review of the new Hematology analyzer validation records and interview with Technical Supervisor the validation records had incomplete data in regards to Accuracy, Precision and Reference range (normal ranges) for the performance specifications of a new analyzer and was not verified before patient testing began on December 15, 2017. (Refer to D5421)
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 new Hematology analyzer validation records and interview with Technical Supervisor the validation records had incomplete data in regards to Accuracy, Precision and Reference range (normal ranges) for the performance specifications of a new analyzer and was not verified before patient testing began on December 15, 2017 The findings include: 1. Review of the new Hematology analyzer validation records revealed the validation records had incomplete data for Accuracy, Precision and Reference range(normal range) and the data was not verified before the analyzer was put into use on December 15, 2017 2. Interview with the Technical Supervisor on January 31, 2018 at 1:00 PM confirmed the validation records had not been thoroughly reviewed to ensure there is complete data for the Accuracy, Precision and Reference range for the performance specifications of the new test system.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of new Hematology analyzer maintenance log from December 15, 2017 through January 31, 2018, review of manufacture instructions, and interview with Technical Supervisor the testing personnel failed to document daily maintenance. The findings include: 1. Record review of the new Hematology daily maintenance log revealed missing documentation of maintenance performed for December 16,17,22,23,24,25,30 and 31 2017 and January 1,6,7,13,14,20,21,27,28 2018 as defined by the manufacture. 2 Review of manufacture instructions indicated, "Daily maintenance tasks- Shutdown." 3. Interview with the Technical Supervisor on January 31, 2018 at 1:30 PM confirmed the manufacture requires a daily shutdow as part of the daily maintenance and the testing personnel did not consistently documented that the daily shutdown was complete.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel training records and interview with the technical supervisor, it was determined that the laboratory director did not ensure all testing personnel had documented training, that included the six mandatory components, for the new hematology analyzer put into use on Dec. 15, 2017. (Refer to D6102)
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated

	that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of testing personnel training records, and on interview with the technical supervisor, determined the laboratory director failed to ensure that the seven (7) testing personnel had initial training documented, that contained the mandatory six (6) components, for the new hematology analyzer prior to being put into use on Dec. 15, 2017. The findings include: 1. A review of the personnel training records revealed that all seven (7) testing personnel had no competencies documented, that contained the mandatory six (6) components for the hematology analyzer put into use on Dec. 15, 2017. 3. An interview with the technical supervisor on Jan. 31, 2018 at 2:00 pm confirmed the laboratory director failed to have documented competency for all testing personnel that contained the required six (6) components for the new hematology analyzer.