Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0702889	07/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Springfield-Greene County Health Department	227 E Chestnut Expressway, Springfield, MO	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Review of the Aptima SARS-CoV-2 Panther System procedure, temperature logs and interview with the technical supervisor (TS), the laboratory failed to define and monitor room temperature for Panther system. Findings: 1. Review of Aptima SARS-CoV-2 Panther System procedure states "room temperature range (15 degrees Celsius to 30 degrees Celsius)". 2. Review of temperature logs showed no documentation of room temperature in 2020 and to date July 21, 2021. 3. Interview with the TS on July 21, 2021 at 10:00 AM confirmed the laboratory failed to define and monitor room temperature for the Panther System.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as

	applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the verification of performance specifications for the Aptima SARS CoV-2 Panther System and interview with the technical supervisor (TS) the laboratory failed to provide documentation for analytic sensitivity and analytical specificity to include interfering substances for the Aptima SARS-CoV-2 Panther system. Findings: 1. Review of Aptima SARS-CoV-2 Panther System verification of performance specifications showed no documentation for analytical sensitivity and analytical specificity prior to patient testing. 2. Interview with the TS on July 21, 2021 at 10:00 AM confirmed the laboratory failed to provide documentation for analytic sensitivity, analytical specificity to include interfering substances for the Aptima SARS-CoV-2 Panther system.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of procedures and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure a procedure was established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency. Findings: 1. Review of procedures showed no procedure available to monitor individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency. 2. Interview with the TS on June 21, 2021 at 9:30 AM confirmed the LD failed to ensure a procedure was established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency.