Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451225	08/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pratt Regional Medical Center	200 Commodore St, Pratt, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) and interview, the laboratory failed to evaluate proficiency testing performance (refer to D5215 and D5221). These are repeat deficiencies from survey conducted 8/3/2018.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) documentation, policies and procedures, and interview with the Technical Supervisor (TS) #5, the laboratory failed to verify the accuracy of hematology, and microbiology analytes that were assigned a proficiency testing score

	that did not reflect the laboratory's test performance. Findings Include: 1. Review of the laboratory's 2018 and 2019 API PT documentation for hematology and microbiology found the following "Not Graded" results: Microbiology 3rd Event 2018: Educational Suseptability ES-03, 11 results. CPL-05 Microbiology 1st Event 2019: Educational Suseptability ES-01, 14 results. CSF Culture MIC SF-01, 12 results. CSF Culture Suseptability SF-01, 12 results. Urine Culture MIC UR-01, 14 results. Microbiology 2nd Event 2019: Educational Suseptability ES-02, 15 results. Hematology 2nd Event 2019: Blood Cell Identification: DIF-02, 4 results, ECI-06,07,08,09,10 Hematology 5C: COU-07 Nucleated RBC. 2. Review of the laboratory's PT review and corrective action forms failed to find any documentation demonstrating a self-assessment or self-grade of the "Not Graded" samples. 3. The TS #5 stated that they performed a review of the "Not Graded" samples but did not document the review, self-assessment, or self-grade performed. The interview occurred 08/29/2019 at 12:05 PM.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2018 and 2019 API PT documentation, policies and procedures, and interview with the TS #5, the laboratory failed to document all proficiency testing evaluation and verification activities for the specialties of immunohematology, microbiology and hematology in 2018 and 2019. Findings Include: 1. Review of the laboratory's 2018 and 2019 APT PT documentation for immunohematolgy had no documentation for evaluation and verification activities by qualfied personnel. a. Immunohematology PT Attestation Statements and Performance Evaluations were signed by TS #5. TS #5 does not meet the qualifications in this specialty. 2. Review of the laboratory's 2018 and 2019 API PT documentation found no testing evaluation or verification activities documented when the laboratory received a grade of "Not Graded" on the following samples: Microbiology 3rd Event 2018 Educational Suseptability ES-03, 11 results. CPL-05 1st Event 2019 Educational Suseptability ES-01, 14 results. CSF Culture MIC SF-01, 12 results. CSF Culture Suseptability SF-01, 12 results. Urine Culture MIC UR-01, 14 results. 2nd Event 2019 Educational Suseptability ES-02, 15 results. Hematology 2019 - 2nd Event: Blood Cell Identification: DIF-02, 4 results, ECI-06,07,08,09,10 Hematology 5C: COU-07 Nucleated RBC 3. The TS #5 stated the laboratory does perform a self evaluation but does not document the actions taken. TS #5 stated he does not qualify in the specialty of immunohematology. The interview occurred 08/29 /2019 at 11:00 AM.
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 on review of the procedure manual and interview, the laboratory failed to provide: 1. Reference ranges for routine chemistry, hematology and urinalysis. Findings include: a. Review of the procedure manual for chemistry did not include reference ranges for 53 analytes. b. Review of the procedure manual for hematology did not include reference ranges for the automated complete blood count. c. Review of the procedure manual for urinalysis did not include reference ranges for routine urinalysis. d. Interview with TS #5 confirmed on August 29,2019 at 2:00 PM the laboratory failed to have reference ranges for chemistry, hematology, and urinalysis in the procedure manuals. 2. Control procedure for manual cell counts using hemocytometer. Findings include: a. Procedue 1256 for Cell Counts on Body Fluids does not include instruction for one control material to be tested each 8 hours of operatation and for patient specimens and control materials testing to be done in duplicate. b. Interview with TS #5 on August 29, 2019 at 10:30 AM confirmed the procedure manual does not include instruction for one control material to be tested each 8 hours of operatation and for patient specimens and control materials testing to be done in duplicate.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a lack of available documentation and confirmed during interview, the laboratory failed to have procedures approved, signed, and dated by the laboratory director before use. Findings: 1. Upon review of the laboratory procedures, the current laboratory director did not approve, sign, and date the laboratory procedures for chemistry. 2. Confirmed during interview with TS #5 on August 29, 2019 at 2:15 PM that the laboratory director had not signed the chemistry procedure manual.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result

	reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on an absence of thermometer records and interview with TS #5, the laboratory failed to define a function check protocol for the thermometers. Findings include: 1. No documentation was available for function checks of thermometers for a 13 month period. No documentation was available for the certification of accuracy (NIST traceble) for thermometers, including blood bank storage thermometers for a 13 month period. 2. Interview with TS #5 on 8/29/19 1:20 pm confirmed the laboratory had no records of function checks for the thermometers used in the laboratory for the past 13 months.