Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451225	04/22/2025
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on discussions on the laboratory's testing list, lack of documentation of histology testing on the CMS 116 and CMS 209, lack of documentation of accuracy checks from 6/15/23 to date of survey, and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of intraprocedure pathology reports (frozen section report) twice a year from 6/15/23 to date of survey. Findings: 1. During the opening survey discussions, the surveyor asked if the laboratory performed frozen section pathology on surgical samples, the general supervisor (GS) #1 stated that she would check with the LD when he arrived. 2. Review of the CMS 116 revealed no listing of histopathology testing and the and CMS209 form revealed no histopathology technical supervisor, general supervisor, or testing personnel. 3. Upon arrival of the LD, the surveyor asked if this laboratory performed frozen sections. The LD confirmed that histology testing of frozen sections. 4. The surveyor requested documentation of test reports and accuracy checks for histology testing. The laboratory provided three reports for 2023 and one report for 2024. 5. Review of "INTRAPROCEDURE/IMMEDIATE CONSULTATION REPORT" and corresponding fixed tissue pathology report on the same patient and tissue samples for the four patients revealed that the testing personnel on both reports was the LD. 6. No review by a different TP or pathologist was provided for the four of four patients tested in 2023 and 2024. 7. Interview with the LD on 4/22/25 at 2:05 p.m. confirmed, the laboratory failed to verify the accuracy of intraprocedure pathology reports (frozen section report) twice a year from 6/15/23 to date of survey.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) performance evaluations, proficiency testing policy, and interview with technical consultant (TC) #1, the laboratory failed to follow their proficiency testing policy and failed to monitor corrective actions for effectiveness for four test events with unacceptable results when clerical error was the documented cause for the failures. Findings: 1. Review of the laboratory's 2023 and 2024 API PT Performance Review and Corrective Action Checklist forms revealed four unacceptable sample results for four separate test events due to clerical errors. a. API 2023 Hematology/Coagulation 1st Event: Sample COU-2 for nucleated RBCs % reported as 1.00 and the expected result range was 10.02-22.29. Cause listed as clerical error. Corrective action entry: "I should pay more attention to unit of measure before reporting out the proficiency testing report for NRBC." b. API 2023 Microbiology 2nd Event: Sample BL-01 for susceptibility interpretation; Linezolid was reported as susceptible but was not an appropriate antibiotic for the sample type. Cause listed as clerical error. Corrective action entry: "Currently, there is no way to electronically transfer susceptibility results to API. Transcribing tech should have another person verify all manually encoded results to API." c. API 2023 Microbiology 3rd Event: Sample BCP-15 for BCID was incorrectly reported as Candida albicans detected, when the expected result should have been not detected. Cause listed as clerical error. Corrective action entry: "Another round of report review will be made post submission of results to make sure all data entries are correct. To reach out to API on how to automate result transmission of BCID results to their website." d. API 2024 Hematology/Coagulation 3rd Event: Sample BFL-03 for manual WBC cell count reported as 19 and the expected result range was 0-18. Cause listed as clerical error. Results had been transcribed from a sticky note and the WBC and RBC values were transposed. Corrective action entry: "Manual result entry will be verified by another tech if they transcribed result to LIS correctly." 2. Review of "Proficiency Testing" policy (effective date of 08/23/19) instructions under the Submission section "A Second personnel will review the submission to report to verify correctness of manually encoded results." a. Policy states results were to be reviewed prior to submission. There was no documentation provided at the time of survey of review by second personnel prior to result submission. 3. Interview with TC #1 on 04/22/25, confirmed the laboratory failed to follow their proficiency testing policy and failed to monitor corrective actions for effectiveness for four test events with unacceptable results when clerical error was the documented cause for the failures.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based upon a tour of the histopathology test area, lack of reagents present in the testing area to examine, lack of reagent lot and expiration date documentation, lack of documentation of what reagent lot was used for histopathology testing and interview with the LD, the laboratory failed to document that the reagents used to perform histopathology testing were within the lot's validity date and not expired. Findings: 1. During a tour of the histopathology test area, the surveyors looked for reagents. No reagents were present in the test area. 2.The surveyors requested documentation of reagent lots and expiration dates for the reagents used for testing. No documentation was provided at the time of survey. 3. Interview with the LD 4/22/25 at 10:35 a.m. confirmed, the laboratory failed to document that the reagents used to perform histopathology testing were within the lot's validity date and not expired.