

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0451225	(X3) Date Survey Completed 06/14/2023
Name of Provider or Supplier Pratt Regional Medical Center	Street Address, City, State 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
D5545	<p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for RecombPlasTin 2G, quality control and quality assessment records for coagulation, observation of the laboratory's ACL TOP 350 and interview, revealed that the laboratory did not follow manufacturer's instructions for International Safety Index (ISI) upon utilizing a new lot number from 2/16/2023 to 6/14/2023 at time of survey. Findings: 1. Quality control and quality assessment records for the ACL TOP 350 coagulation analyzer on 06/14/2023 determined the Prothrombin Time (PT) and International Normalized Ratio (INR) for patients could be affected with the current lot of RecombPlasTin 2G in use. 2. The manufacturer's current lot of RecombPlasTin 2G (N0925455 Exp: 09/2024) listed the ISI for the ACL TOP family/ACL TOP family 50 Series as 0.97. 3. The ACL TOP 350 being utilized in the laboratory for PTs and International Normalized Ratio (INR)s had the ISI listed as 1.00. 4. From 2/16/2023 through 6/14/2023 there were 1625 PTs and INRs reported on patients with the incorrect ISI in the ACL TOP 350 for the current lot number of RecombPlasTin 2G. 5. Interview with Technical Consultant #1, General Supervisor #4 and the Laboratory Director on 6/14/2023 at 10:15 a.m. confirmed, the laboratory failed follow manufacturer's instructions for the International Safety Index (ISI) upon utilizing a new lot number for RecombPlasTin 2G from 2/16/2023 to 6/14/2023.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p>

(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:

Based on review of quality control (QC) records and calibration records for gentamicin performed on the Beckman Coulter Access2i SN: 5063 (Access i) chemistry analyzer and tobramycin on the Beckman Coulter Access2 SN: 7143 (Access2) from 5/2/23 to 5/3/23, lack of patient remediation documentation for gentamicin and tobramycin patient results and interview with GS #3, the laboratory failed to evaluate and document patient results since the last acceptable QC test run to determine if patient results had been adversely affected and may require corrective action. Findings: 1. Review of gentamicin QC records and gentamicin calibration records from the Accessi chemistry analyzer revealed unacceptable QC values on 5/3/23. Repeat QC testing did not resolve the issue. The gentamicin assay required calibration, was acceptable and the repeated QC was acceptable. 2. Review of tobramycin QC records and tobramycin calibration records from the Access2 chemistry analyzer revealed unacceptable QC values on 5/3/23. Repeat QC testing did not resolve the issue. The tobramycin assay required calibration, was acceptable and the repeated QC was acceptable. 3. Prior to the calibration restoration in items #1 and #2, the last acceptable QC was obtained on 5/2/23. 4. No documentation to demonstrate gentamicin and tobramycin patient testing was performed or results evaluated for possible corrective action was provided at the time of survey. No corrective action documentation was present including notification to the provider and patients of results, and orientation/training for the performing test personnel was provided at the time of survey. 5. Review of patient test results revealed no patient results were reported without evaluation for the unacceptable QC and calibration. 6. Interview with GS #3 on 6/14/23 at 3:30 p.m. confirmed, the laboratory failed to evaluate and document any patient remediation of gentamicin and tobramycin patient results since the last acceptable test run to determine if patient results had been adversely affected and may require corrective action.