

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0451225	(X3) Date Survey Completed 10/14/2021
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
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs, and interview with General Supervisor #1(GS1), the laboratory failed to document review and all corrective actions taken when the criteria for proper storage of chemistry reagents and calibrators as specified under 493.1252(b), were not met. Findings: 1. Review of the laboratory's Kenmore Refrigerator/Freezer temperature logs for December 2020 through August 2021 titled "QUALITY CONTROL (ENVIRONMENTAL)" revealed the laboratory's established "TEMP. RANGE" listed on the log for the freezer was "-15 TO -20 (degrees) C". This range is the stated temperature requirement for Synchron Multi Calibrator and Synchron Enzyme Validator Set Levels 1 & 2 found stored in this freezer. 2. Log entries for December 2020 contained 25 of 31 entries where the temperature recorded was higher than -15 (degrees) Celcius (C). 3. Log entries for January through March 2021 contained 79 of 90 entries where the temperature recorded was higher than -15 (degrees) C. 4. Log entries for April through June 2021 contained 66 of 91 entries where the temperature recorded was higher than -15 (degrees) C. 5. Log entries for July through August 2021 contained 46 of 62 entries where the temperature recorded was higher than -15 (degrees) C. 6. No documentation of review was on the forms from December 2020 through August 2021. 7. No corrective action entries were on the forms from December 2020 through August 2021. 8. Interview with GS1 on October 14, 2021 at 11:55 a.m. confirmed, the laboratory failed to document review and all corrective actions taken when the criteria for proper storage of chemistry reagents and calibrators as specified under 493.1252 (b), were not met.</p>

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the review of the maintenance logs for the DXH600, IRIS, and Aution Max, lack of TC or GS review documentation and interview revealed the laboratory failed to document all analytic system assessment activities. Findings: 1. Maintenance logs for the DXH 600 hematology analyzer had no review documentation from September 1, 2019 to date of survey. 2. Maintenance logs for the IRIS urinalysis analyzer had no review documentation from September 1, 2019 to date of survey. 3. Maintenance logs for the Aution Max urinalysis analyzer had no review documentation from September 1, 2019 to date of survey.. 4. Interview with GS#1 on October 14, 2021. confirmed, the laboratory failed to document all analytic system assessment activities.