

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0451225	(X3) Date Survey Completed 08/03/2018
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) policy and procedure, American Proficiency Institute (API) proficiency testing documentation, hematology instrument result printouts, staff schedules, and interview with the Technical Supervisor (TS), the laboratory failed to test the 2017 3rd testing event hematology samples the same number of times that it routinely tests patient samples. Findings Include: 1. Review of the laboratory's policy and procedure titled "PROFICIENCY TESTING" states: "B. All surveys are to be treated and tested only in accordance with the written directions and in accordance with all CLIA regulations." 2. Review of the laboratory's API PT documentation for the 3rd testing event of 2017 in the specialty of hematology found Testing Personnel (TP) #3 signed the attestation form stating they performed analysis on PT sample COU-12 on 11/20/2017. The API PT due date for the hematology/coagulation 3rd testing event of 2017 was 12/01/2017. 3. Review of the laboratory's hematology instrument printouts included with the API PT documentation found three separate analyses of PT sample COU-12: Sample ID: API COU-12 Date: 11/20/2017 Time: 07:52 Sample ID: 17API_COU-12 Date: 11/29/2017 Time: 15:31 Sample ID: 17API_COU-12 Date: 11/29/2017 Time: 15:34 3. Review of the laboratory's staff schedule found that TP #3 was not scheduled to be present in the laboratory on 11/29/2017 at 15:30. The schedule states that TP #3's shift ended at 14:30 on 11/29/2017. 4. The TS confirmed that it is not routine laboratory practice for a patient's sample to be reanalyzed nine days after the first analysis by a different TP. The TS stated they were unable to provide any laboratory policies or procedures that stated patient samples would be handled in a manner similar to the testing process described above. The interview occurred 08/03/2018 at 12:05 PM.</p>

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, 2017 and 2018 proficiency testing documentation, and interviews with the Technical Supervisor (TS) and anonymous Testing Personnel (TP), the laboratory failed to document and maintain documentation of the handling, preparation, processing, examination, and each step of the testing and reporting of results for all proficiency testing (PT) samples for a minimum of two years from the date of the proficiency testing event. Findings Include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation for 2017 and 2018 found the following altered results: Hematology 2018 - 1st Testing Event: Blood Cell Identification: Sample BCI-01 "Lymphocyte, normal" crossed out, "Hairy Cell" filled in - no testing documentation located Fibrinogen instrument printout results unreadable, results handwritten on instrument printout - laboratory unable to locate electronic copy of results or readable printout of results 2017 - 3rd Testing Event: Urinalysis & HCG: Samples UA-05 and UA-06 Result UA-05: 1.009 crossed out, 1.025 written below Result UA-06: 1.009 crossed out, 1.015 written below No documentation explaining the 1.009 results located Coagulation: Samples COA-11, COA-12, COA-13, COA-14, and COA-15 Fibrinogen instrument printout results unreadable, results handwritten on instrument printout - laboratory unable to locate electronic copy of results or readable printout of results Chemistry 2017 - 2nd Testing Event: Body Fluid Crystals: Sample CYS-04 Laboratory log sheet: dated 10/19/2017 and result "Calcium oxalate (dehydrate) crystals observed" documented API Result Form: result "Calcium oxalate crystal(s)" crossed out, "Crystals seen, referred for ID" filled in - corrections dated 11/2/17 Cell Count: Sample BFL-04 Laboratory log sheet: Count 1: WBC - 94 Count 2: WBC - 100 API Result Form: WBC (manual-CSF/BF) result of 83 crossed out, 94 written above - no documentation explaining the 83 result located 2017 - 1st Testing Event: Blood Gas: Sample BG-03 API Result Form: pH 7.43 crossed out, 7.26 written above pCO2 18 crossed out, 54 written above pO2 227 crossed out, 159 written above Original results (crossed out) dated 2/6/17 and initialed by TP #3, results written above dated 2/7 and initialed by TP #6 No instrument printout for the original results dated 2/6/17 located. Immunology/Immunohematology 2017 - 2nd Testing Event: CRP Quantitative: Sample QCP-04 Result QCP-04: 0.1 crossed out, 6.5 written above - no documentation explaining the 0.1 result located 2. Review of the laboratory's policy and procedure titled "PROFICIENCY TESTING" found no mention or reference to PT documentation retention requirements or practices. 3. Anonymous TP stated the TP submit the instrument printouts from PT analysis and the completed API bubble sheets to the TS. The TP stated they did not participate in PT result submission after that point. The TP further stated that the TS would, on occasion, come back and

ask the TP to rerun the PT samples after reviewing the instrument printout and bubble sheets the TP had submitted to the TS. The anonymous interviews occurred 08/03/2018 at 11:30 AM. 4. The TS confirmed the TP submitted the instrument printouts and completed API bubble sheets to them but was unable to provide an explanation for the results missing instrument printouts or the numerous changes to the results. The interview occurred 08/03/2018 at 12:20 PM.

D2087

ROUTINE CHEMISTRY

CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's 2018 American Proficiency Institute (API) proficiency testing (PT) documentation and documentation by the Technical Supervisor (TS), the laboratory failed to attain a score of at least 80 percent of acceptable responses for the pO2 analyte resulting in unsatisfactory analyte performance for the 2nd testing event of 2018. Findings Include: 1. Review of the laboratory's API PT documentation for the 2nd testing event of 2018 found the laboratory scored a 60 percent for the analyte pO2 after obtaining unacceptable results for samples BG-07 and BG-09. 2. The TS confirmed the laboratory received unacceptable scores for the pO2 analyte on samples BG-07 and BG-09 on the PT corrective action worksheets completed on 07/26/2018.

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 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) documentation, policies and procedures, and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy of hematology, microbiology, and chemistry 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 2017 and 2018 API PT documentation for hematology, microbiology, and chemistry found the following ungraded results: Hematology /Coagulation: 2018 - 1st Testing Event: Received "Grade" of "Not Graded" Blood Cell Identification: BCI-06, BCI-07, BCI-01 Body Fluid Crystals: CYS-02 Hematology 5C: COU-01 (Nucleated RBCs) 2017 - 3rd Testing Event: Received "Grade" of "Not Graded" Blood Cell ID: BCI-20, BCI-21 2017 - 1st Testing Event: Received "Grade" of "Not Graded" Blood Cell ID: BCI-06, BCI-07 Body Fluid Cell Count: BCF-01 (RBC and WBC) Hematology 5C: COU-01 (Nucleated RBCs) Urinalysis & HCG: UA-02 (urobilinogen) Microbiology 2018 - 2nd Testing Event: Received "Grade" of "Not Graded" Educational Susceptibility: ES-02 Urine Culture & Colony Count: UR-06 (MIC Testing/Piperacillin/Tazobactam) 2018 - 1st Testing

Event: Received "Grade" of "Not Graded" Educational Susceptibility: ES-01 2017 - 3rd Testing Event: Received "Grade" of "Not Graded" Educational Susceptibility: ES-03 2017 - 1st Testing Event: Received "Grade" of "Not Graded" Educational Susceptibility: ES-01 Chemistry 2018 - 1st Testing Event: Received "Grade" of "Not Graded" Urine Drug Screen: UDS-02 (UDS Opiates) 2017 - 1st Testing Event: Received "Grade" of "Not Graded" Cardiac Markers: CH-01 (Triglycerides) Chemistry (Endocrinology): CH-01 (Free Thyroxine) 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. Review of the laboratory's policy and procedure titled "PROFICIENCY TESTING" failed to find any direction or statements requiring a documented self-assessment or self-graded on PT samples that received a grade of "Not Graded." 4. The TS 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 08/03/2018 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 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) documentation, policies and procedures, and interview with the Technical Supervisor (TS), the laboratory failed to document all proficiency testing evaluation and verification activities for the specialties of chemistry and hematology in 2017 and 2018. Findings Include: 1. Review of the laboratory's 2017 and 2018 API PT documentation found the laboratory received a grade of "Unacceptable" on the following samples: Chemistry 2018 - 2nd Testing Event: Blood Gas: BG-07 (pCO₂, pO₂), BG-09 (pO₂) Blood Oximetry: BLX-08 (Carboxyhemoglobin %, hemoglobin) Chemistry: CH-06 (Phosphorous), CH-07 (Phosphorous), CH-08 (Total Protein), CH-09 (Phosphorous) Chemistry (Endocrinology): CH-06 (Thyroid Stimulating Hormone) 2018 - 1st Testing Event: Cardiac Markers: CM-01 (CK, Total) Chemistry: CH-01 (Chloride, LDL Cholesterol, Phosphorous, Sodium), CH-04 (LDL Cholesterol), CH-05 (Phosphorous) Chemistry (TDM): CH-03 (Acetaminophen, Tobramycin) Immunoassay 2: IAT-01 (25-OH Vitamin D) Urine Chemistry: UC-02 (Urine Sodium) Urine Drug Screen: UDS-03 (Oxycodone) 2017 - 3rd Testing Event: Chemistry: CH-11 (LDL Cholesterol) Chemistry (Endocrinology): CH-12 (HCG serum-quant) 2017 - 2nd Testing Event: Cell Count (Manual): BFL-03 (RBC manual - CSF/BF), BFL-04 (RBC manual - CSF /BF) Immunoassay 2: IAT-05 (25-OH Vitamin D) 2017 - 1st Testing Event: Blood Gas: BG-01 (pO₂) Cardiac Markers: CM-05 (BNP) Chemistry (Endocrinology): CH-02 (HCG serum-quant) Chemistry (TDM): CH-05 (Acetaminophen, Phenytoin) Urine Drug Screen: UDS-01 (Cocaine Metabolites, Opiates, Tricyclic Antidepressants) Hematology 2017 - 1st Testing Event: Blood Cell Identification: BCI-02 Hematology 5C: COU-02 (Reticulocyte) PPM/Urine Sediment: US-01 Sedimentation Rate: ESR-02 2. Review of the laboratory's corrective action documentation found the laboratory identified the probable issues and/or errors but failed to document the corrective action taken to address or prevent the identified errors. 2018 - 2nd Testing Event: "Mixing problem is probable most responsible for the error." "Specimen processing & handling is probable most responsible for the error." "Mixing problem is probable most responsible for the error." "Sample handling and preparation are probable most

responsible for the error." 2018 - 1st Testing Event: "Mixing problem is probable most responsible for the error." "Mixing is probable most responsible for the error." "Clerical error. Should have been positive." "Specimen Mixing is probable most responsible for the error." "Mixing problem is probable most responsible for the error." "Several tests in this CH-01 went a little bit high from expected result which suggests that mixing is probable most responsible for the error." "Mixing problem is probable most responsible for the error." 2017 - 3rd Testing Event: "Result should be 1235.78 w/c is very close to the group mean of 1240.4." 2017 - 2nd Testing Event: "Results suggest interchange of survey bottle or samples." "Mixing problem is probable most responsible for the error." 2017 - 1st Testing Event: "Mixing problem is probable most responsible for the error." "Handling and preparation of specimen is probable most responsible for the error." "Mixing problem is probable most responsible for the error." "Mixing problem is probable most responsible for the error." "Mixing problem is probable most responsible for the error." "Mixing problem is probable most responsible for the error." "Clerical error." "Printed the wrong methodology." Hematology 2017 - 1st Testing Event: "Confused by the eccentric nucleus that looks like nucleus of metamyelocyte. Should look to the size and cytoplasm next time." "Mixing problem is probable most responsible for the error." "Mixing problem is probable most responsible for the error." 3. Review of the laboratory's policy and procedure titled "PROFICIENCY TESTING" found directions for investigating and identifying the source of the error and/or problems but failed to provide direction on performance or documentation of corrective actions. 4. The TS stated the laboratory does take corrective actions to address the errors and/or issues identified with PT but does not document the corrective actions taken. The interview occurred 08/03/2018 at 12:00 PM.