Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D1044822	11/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Regional Medical Laboratory, Inc - Sek	2401 S Tucker, Suite 5, Pittsburg, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and interview, the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples. Findings: 1. Review of the laboratory's 2019 PT documentation found the laboratory was testing PT samples multiple times as follows: 2019 - 2nd Testing Event Hematology /Coagulation. Five Hematology samples: XE-06, -07, -08, -09, and -10 were analyzed for 16 reported parameters of the Complete Blood Count (CBC): Red Bloodcell Count (RBC), Hemoglobin, Hematocrit, Platelet, White Bloodcell Count (WBC), Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, MCH, MCHC, MCV, MPV, RDW-CV and RDW-SD. XE-06 CBC performed 2 times XE-07 CBC performed 2 times XE-08 CBC performed 3 times XE-09 CBC performed 2 times XE-10 CBC performed 2 times 2. The Laboratory Director (LD) stated the laboratory does not rerun patients unless it is abnormal or rerun is requested, and testing is not routinely done in duplicate. Interview with LD on November 13, 2019 at 11:40 a.m. confirmed, the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a

	maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on the lack of documentation and interview, the laboratory failed to establish and follow a routine accuracy check for the thermometers and centrifuges. Findings: 1. Request was made for the accuracy check records for the 5 thermometers used in the laboratory. Only 1 of 5 documents was made available at the time of survey. 2. Request was made for the accuracy check records for 3 centrifuges used in the laboratory. No records were available at the time of survey. 2. Interview with the LD on November 13, 2019 at 1:20 p.m. confirmed, the laboratory failed to establish and follow a routine accuracy check for the thermometers and centrifuges.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the review of the Beckman AU450 chemistry analyzer calibration verification records of 24 analytes and interview, the laboratory failed to perform calibration verification once every six months for 16 of 24 analytes. Findings: 1. Review of the calibration verification records for the analytes calcium, glucose, creatinine, magnesium, phosphorus, blood urea nitrogen (BUN), and triglyceride revealed the laboratory performed the calibration verifications on March 21, 2019 but failed to perform the calibration verifications that were due in September 2019. No other calibration verification data performed in 2019 for the listed analytes was availible at the time of survey. 2. Review of the calibration verification records for the analytes ALT, AST, Alk Phos, LDH revealed the laboratory performed the calibration verifications on October 25, 2018 but failed to perform the calibration verifications that were due in April 2019. Calibration verifications for the listed analytes were

	performed on July 24, 2019. 3. Review of the calibration verification records for the analytes Iron, Sodium, Potassium, Chloride and Carbon Dioxide (CO2) revealed the laboratory performed the calibration verifications on September 26 and 28, 2018 but failed to perform the calibration verifications that were due in March 2019. Calibration verifications for the listed analytes were performed on July 24 and 26 2019. 4. Interview with the LD on November 13, 2019 at 1:00 p.m. confirmed, the laboratory failed to perform calibration verification once every six months for 16 of 24 analytes.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's individualized quality control plan (IQCP), and quality control documentation, the laboratory failed to ensure the quality control testing for the Acceava Mono test was performed according to the IQCP requirements. Findings: 1. Review of the laboratory's IQCP documentation titled "Acceava Mono Test Kit Quality Control Plan" included a section for external positive and negative quality control (QC) frequency as "New lot, new shipment, new operator, and every 30 days." 2. Review of the Mono Worsheet included: a. QC performed on January 8, 2019, March 11, 2019, May 20, 2019, July 12, 2019, and August 14, 2019. b. Patient and Proficiency testing done without QC performed as required occured in: February - 13 patients, April -10 patients and 5 proficiency samples, May - 4 patients prior to QC performance date, July - 1 patient prior to QC performance date 3. Interview with the Technical Consultant on November 13, 2019 at 11:00 a.m.confirmed, the laboratory failed to ensure the quality control testing for the Acceava Mono test was performed according to the IQCP requirements.