Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0664296	09/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Samc Laboratory Services Oncology Sindelar	10050 Kennerly Road, Saint Louis, MO	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the 2018, 2019 proficiency testing (PT) results and interview with the technical consultant (TC) #1, the laboratory failed to enroll in a PT program for the following regulated analytes: white blood cell (WBC) count, red blood cell (RBC) count, hemoglobin (HGB), hematocrit (HCT), platelet count (PLT), white blood cell (WBC) differential. Findings: 1. Review of the third PT event for 2018 and the first and second PT event of 2019 showed no results reported by the PT provider for the analytes: WBC, RBC, HGB, HCT, PLT, and WBC differential. 3. Interview with the TC #1 on September 24, 2019 at 11:30 AM confirmed the laboratory failed to enroll in PT for the analytes, WBC, RBC, HGB, HCT, PLT, and WBC differential for the third event of 2018 and the first and second event of 2019.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical consultant (TC) #1, the laboratory failed to have a written procedure for quality control (QC), proficiency testing (PT), and usage of citrate tubes on the Beckman Coulter AcT diff 2 hematology analyzer for complete blood cell counts. Findings: 1. Review of the procedure manual showed no procedure for QC, PT, and usage of citrate tubes for complete blood cell counts. 2. Interview with the TC #1 on September, 24, 2019 at 11: 00 AM confirmed the laboratory failed to have a written procedure for QC, PT, and usage of citrate tubes for complete blood cell counts available to laboratory personnel.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's manual and interview with testing personnel (TP) #3, the laboratory failed to monitor and document the humidity of the laboratory for proper operation of the Beckman Coulter AcT diff 2. 1. Review of the manufacturer's manual for performance specifications revealed "humidity no higher the 85 percent without condensation." 2. Review of the room temperature documentation logs showed the laboratory failed to document humidity. 3. Interview with the TP #3 on September 24, 2019 at 11:00 AM confirmed the laboratory failed to document the humidity in the laboratory.
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 review of hematology calibration records for the Beckman Coulter AcT diff 2 analyzer, review of the procedure manual and interview with the technical consultant (TC) #1, the laboratory failed to perform calibration verification activities on the hematology analyzer for complete blood cell counts at least once every six months for 2018 and when major preventive maintenance or replacement of critical parts were performed. Findings: 1. Review of the calibration records for the AcT diff 2 for 2018 revealed the laboratory failed to perform 2 of 2 calibrations for the required 6 month interval. 2. Review of the maintenance records for the AcT diff 2 revealed on May 6, 2019 major components(lyse fluidic sensor, bath diluent filters, hemoglobin lamp) for the hematology analyzer were replaced. Calibration was not performed after this replacement of critical parts. 3. Review of the procedure manual revealed a policy to "perform calibration procedures when you replace any AcT component that involves the primary measurement characteristics." 4. Interview with the TC #1 on September 24, 2019 at 11:30 AM confirmed the laboratory failed to perform calibration of the hematology analyzer every six months for 2018 and after replacement of critical parts that may influence test performance.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the procedure manual for quality assessment (QA) and interview with the technical consultant (TC)#1, the laboratory failed to establish a procedure to monitor, access, and identify problems in the postanalytic system. Findings: 1. No QA procedure was available for review. 2. Interview with the TC #1 on September 24, 2019 at 11:30 AM confirmed the laboratory failed to establish a procedure for an ongoing mechanism to monitor, access, and correct problems in the postanalytic system.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 personnel documentation and interview with the technical consultant (TC) #1, TC #1 and #2 failed to perform two of four competency evaluations semiannually the first year of employment. Findings: 1. Review of 2018,

	2019 employee competencies revealed TC #1 and #2 failed to perform competency evaluations for testing personnel (TP) #2 and #3 of moderate complexity testing semiannually the first year of employment. 2. Interview with the TC #1 on September 24, 2019 at 11:00 AM confirmed TC #1 and #2 failed to perform annual competency evaluations for 2 TP semiannually during the first year of testing.