Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0979524	10/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Augusta Oncology Associates	1303 D'Antignac Street, Suite 1000, Augusta, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 17, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and interviews with TP #3 (CMS 209) and the clinic's administrator, the laboratory failed to rotate testing personnel (TP) for PT testing in the specialties of Hematology/coagulation and Chemistry for 2017 and 2018. Findings include: 1. American Proficiency Institute (API) PT document review and staff interview revealed that, the same testing personnel (TP # 2, #3) tested all PT samples. TP #s 4 through # 7 did not participate in PT testing in 2017 and 2018. 2. An interview with Staff #3 (CMS 209) and the clinic's administrator in the conference review room on 10/17/2018 at approximately 01:00 pm confirmed only TP #2 and #3 tested all PT samples in 2017 and 2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on the review of laboratory maintenance records and interviews with TP #3 (CMS 209) and the clinic's administrator, the laboratory failed to calibrate the Horizon Model 642 Mini E centrifuge Bi-annually per manufacturer's recommendations. Findings include: 1. Observation during the laboratory tour revealed the LabCorp Horizon model 642 Mini E centrifuge was last calibrated on October 23, 2015. 2. An interview with TP # 3 (CMS 209) and clinic's administrator October 17, 2018 in the conference review room at approximately 01:18 PM, confirmed the centrifuge had not been calibrated since 10/23/2015.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records and interviews with both TP # 3 (CMS 209) and the clinic's administrator, the laboratory's Technical Consultant(TC) failed to include the six required competency assessment criteria when evaluating annual competency on testing personnel in 2017 and 2018 for the specialties of Hematology/ Coagulation and Chemistry. The findings include: 1. Review of testing personnel (TP #s 2 - 7 on CMS 209) competency assessment records for 2017 and 2018 revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. An interview with TP # 3 (CMS 209) and the clinic's administrator in the conference review room on October 17, 2018 at approximately 01:20 PM confirmed that annual competency assessment for testing personnel (TP#s 2-7, CMS 209) did not contain the six required criteria by CLIA.