Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0707117	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Wellstar Medical Group Spalding Oncology	**Street Address, City, State** 230-D West College St, Griffin, 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 May 23, 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:
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on document review and staff interview, the lab failed to review proficiency test (PT) results when received from the PT provider. Findings include: 1. Review of the American Association of Bioanalysts (AAB) PT score sheets revealed the lack of result review for 2017 events 1, 2, and 3. 2. Interview with staff #3 (CMS 209 form) on 5/23/18 at 1:40 PM in the lab, confirmed the lack of review.
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 temperature documents, manufacturer requirements, and staff interview, the lab failed to monitor and record room temperature (RT) and relative humidity (RH) in the laboratory. Findings include: 1. Review of temperature chart documents for August 2016- May 2018 to date revealed the lab was not monitoring the RT or RH in the lab area. 2. Review of the manufacturer's requirements revealed the RT and RH must be maintained. 3. Interview with staff #2 and #3 (CMS 209 form) on 5/23/18 at 2:10 PM in the lab area, confirmed the RT and RH were not monitored or documented.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview , the technical consultant (TC) failed to perform annual competency on all testing personnel. Findings include: 1. Review of TP documents revealed the TC failed to perform competency evaluation on TP for the year of 2017. 2. Interview with staff #3 (CMS 209 form) on 5/23/18 at 1:48 PM in the lab area, confirmed the TC did not perform competency in 2017.