Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1024090	(X3) Date Survey Completed 07/30/2018
Name of Provider or Supplier American Oncology Partners, Pa	**Street Address, City, State** 4700 Waters Avenue, Suite 201, Savannah, 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 July 30, 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:
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records, review of the Laboratory Personnel Report Form (CMS 209), and staff interview, the laboratory failed to rotate performance of quality control (QC) samples among all personnel who test patient samples. Findings include: 1. Review of QC records records revealed all QC samples in 2017 and 2018 were tested by testing personnel # 1 (see CMS 209). 2. Review of the CMS 209 revealed 12 additional employees listed as testing personnel. 2. Interview with testing personnel #1 (see CMS 209) on July 30, 2018 at 11:00 am confirmed testing personnel # 1 performed testing on all QC samples in 2017 and 2018 and the twelve testing personnel perform testing on patient samples...
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test

	results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation by the surveyor and review of instrumentation used in the laboratory to perform testing in the speciality of hematology, review of laboratory records and staff interview, the laboratory failed to have a system in place that , twice a year, evaluates and compares results of values obtain on the two hematology analyzers. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed the laboratory uses two different hematology analyzers. The Medonic M series is used in the chemotherapy infusion area and the Emerald Cell Dyn is used in the laboratory area. 2. Review of patient test records revealed both analyzers are used for patient testing. 3. Review of laboratory records revealed no documentation or records showing the laboratory performed comparative testing between the two analyzers. 4. Interview with testing personnel # 1 (see CMS 209) on July 30, 2018 at 10:30 am in the laboratory director's office confirmed the laboratory does not perform comparison studies.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel assessment policy, review of competency assessment records and staff interview, the laboratory director failed to ensure the laboratory's competency assessment policy and procedures included annual review of all testing personnel and initial, semi-annual and annual review of newly hired testing personnel. Finding include: 1. Review of the laboratory's personnel assessment policy found on page 2 of the Quality Assessment Plan revealed no instructions for initial, semi-annual and annual competency assessment of testing personnel by the technical consultant/laboratory director. 2. Review of competency assessment records revealed documentation for only 3 of 13 personnel listed on the CMS 209 . No documentation of competency assessment is available for 10 of 13 employees. 3. Interview with testing personnel # 1 (see CMS 209) on July 30, 2018 in the laboratory director's office at 12 pm confirmed the policy does not include instructions for the required competency assessment of all testing personnel.
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 207 and 2018 personnel competency assessment records, review of the laboratory personnel report form (CMS 209), and staff interview, the technical consultant failed to perform competency assessment on 10 of 13 employees. Findings include: 1. Review of the CMS 209 revealed 13 employees listed as testing personnel. 2. Review of personnel competency assessment records revealed no documentation of competency assessment for 10 of 13 testing personnel. No annual competency assessment is available for 6 of the 13 testing personnel listed on both the CMS 209 form dated 7/27/16 and the form dated 7/30/18 and no documentation of initial, semi-annual or yearly competency assessment is available for 4 of 4 employees who started testing after the survey performed on 7/27/16. 3. Interview with testing personnel # 1 (see CMS 209) on July 30, 2018 at 12 pm in the laboratory director's office confirmed annual competency was not performed on testing personnel # 4, 5, 6, 7, 8 & 13 and initial, semi-annual and annual competency assessment was not performed for testing personnel # 9, 10, 11, & 12.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records, comparison of the Laboratory Personnel Report forms (CMS 209) for surveys performed in 2016 and 2018 and staff interview, the laboratory failed to have documentation of training for 4 of 4 employees who started testing after the July 27, 2016 survey. Findings include: 1. Comparison of the CMS 209 for the July 27, 2016 survey and the CMS 209 for the July 30, 2018 survey revealed 4 new testing personnel (TP) listed on the 2018 form, TP # 9, 10, 11 & 12.. 2. Review of personnel records revealed no documentation of training other than statements signed by the laboratory director dated January 18, 2017 and February 9, 2018 listing testing personnel who have been trained and are qualified to perform testing. 3. Interview with TP # 1 (see CMS 209) on July 30, 2018 at 11:30 am in the laboratory director's office confirmed training records for the four new TP are not available.