Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D0714409	**(X3) Date Survey Completed** 02/08/2019
Name of Provider or Supplier Clinical Oncology Associates	**Street Address, City, State** 30160 Orchard Lk Rd Suite 100, Farmington Hills, MI	
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**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on review of the 2016, 2017, and 2018 provider performance testing reported to the CLIA database and review of the final reports from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for two consecutive events for white blood cell differential, hemoglobin, white blood cell, and platelets and for four of eight consecutive events for the red blood cell count, hematocrit, and the overall specialty of hematology. Refer to 2130 and D2131.
D2130	HEMATOLOGY

	CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on review of data from proficiency testing (PT) reports and the laboratory's PT results from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance in two consecutive events for the white blood cell differential (WBC diff), hemoglobin (HGB), white blood cell (WBC), and platelet (PLTS) analytes. Findings include: WBC diff PT Event Score 2nd event 2018 0% 3rd event 2018 0% HGB PT Event Score 2nd event 2018 0% 3rd event 2018 0% WBC PT Event Score 2nd event 2018 0% 3rd event 2018 0% PLTS PT Event Score 2nd event 2018 0% 3rd event 2018 0% The laboratory failed to achieve satisfactory performance in four of eight testing events for the analytes red blood cell (RBC) and hematocrit (HCT) constituting a subsequent occurrence of unsuccessful participation in PT. RBC PT Event Score 2nd event 2016 0% 1st event 2017 40% 2nd event 2018 0% 3rd event 2018 0% HCT PT Event Score 2nd event 2016 0% 1st event 2017 60% 2nd event 2018 0% 3rd event 2018 0%
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on a review of the Proficiency Testing (PT) data report (CASPER Report 155D) and PT results from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for the specialty of hematology in four of eight testing events. Findings include: Unsatisfactory performance for four of eight testing events constitutes subsequent unsuccessful performance for the specialty of hematology. Hematology PT Events Score 2nd event 2016 0% 1st event 2017 73% 2nd event 2018 0% 3rd event 2018 0%