

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2165187	(X3) Date Survey Completed 12/06/2022
Name of Provider or Supplier American Oncology Partners, Pc DbA Hematology-	Street Address, City, State 8550 Naab Rd, Suite 205, Indianapolis, IN	
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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to achieve a Proficiency Testing (PT) score of at least 80 percent (satisfactory performance) for two out of three consecutive testing events for the analyte white blood cell differential (event 3 in 2021 and event 2 in 2022). (See 2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>

events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to achieve a Proficiency Testing (PT) score of at least 80 percent (satisfactory performance) for two out of three consecutive testing events for the analyte white blood cell differential (event 3 in 2021 and event 2 in 2022). Findings Included: 1.) Review of American Proficiency Institute PT records revealed the following: A.) "Performance Summary 2021 Hematology / Coagulation- 3rd Event" showed the following scores: 1.) Hematology a) White Blood Cell Differential - 0% b.) Basophils 0% c.) Eosinophils-0% d.) Lymphocytes -0% e.) Monocytes -0% f.) Neutrophils-0% B.) "Performance Summary 2022 Hematology / Coagulation - 2nd Event" showed the following scores: 1.) Hematology a) White Blood Cell Differential - 0% b.) Basophils 0% c.) Eosinophils-0% d.) Lymphocytes -0% e.) Monocytes -0% f.) Neutrophils-0% 2.) During interview on 12/6/2022 at 2:29 PM, SP-1 (technical consultant) confirmed the laboratory had two PT event failures for white blood cell differential. 3) Annual test volume for white blood cell differential is 15,274.