

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D2154943	<b>(X3) Date Survey Completed</b>  05/26/2021
<b>Name of Provider or Supplier</b>  American Oncology Partners Pa	<b>Street Address, City, State</b>  2855 E Magic View Dr Ste B, Meridian, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of training documentation and competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview on 5/26/2021 with the Technical Consultant (TC), the laboratory failed to establish and follow written policies and procedures to assess testing personnel in accordance with 42 C.F.R. 493.1413(b)(7)(8). The findings include: 1. A review of training and competency records identified one (1) of one(1) testing personnel listed on the CMS 209 failed to have documentation of annual competency for 2020 which included the six parameters as listed in 493.1413(b)(7)(8). 2. An interview with the TC on 5/26/2021 at 9:29 am confirmed the above findings.</p>
<b>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on record review of instrument verifications and an interview with the Technical Consultant (TC) on 05/26/2021, the Laboratory Director (LD) failed to ensure that verification procedures that were used for verification of the Beckman</p>

Coulter DXH 520 were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method before their use in patient testing. The findings include: 1. A record review of the Beckman Coulter DXH 520 verification performed in July 2020, identified that the Laboratory Director failed to approve verification of performance of complete blood count testing before implementation of patient testing. 2. An interview with the TC on 05/26/2021 at 10:40 am confirmed that the LD failed to approve and sign the performance verification of the Beckman Coulter DXH 520 before patient testing was implemented. 3. The laboratory reports performing 12,612 complete blood count tests annually.