

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2168975	<b>(X3) Date Survey Completed</b>  06/07/2022
<b>Name of Provider or Supplier</b>  American Oncology Partners, Pa	<b>Street Address, City, State</b>  41201 Schadden Road, Suite 2, Elyria, OH	
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>D6033</b>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with Technical Consultant (TC) #1, TC#2 failed to meet the minimum qualification requirements of 493.1411 of this subpart. All 200,075 patients tested in this laboratory in the specialty of Hematology had the potential to be affected by this deficient practice. Findings Include: 1. TC#2 failed to meet the minimum qualification requirements. (Refer to D6035) 2. A qualified TC failed to assess the competencies of testing personnel (TP) #1, TP#2 and TP#3 in 2020, 2021 and 2022 assuring their competency was maintained in order to perform moderately complex hematology testing procedures and report the test results promptly, accurately, and proficiently. (Refer to D6046)</p>
<b>D6035</b>	<p><b>TECHNICAL CONSULTANT QUALIFICATIONS</b> CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State</p>

in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:  
 Based on record review and an interview with Technical Consultant (TC) #1, TC#2 failed to have met the minimum qualification requirements. All 200,075 moderately complex hematology testing procedures conducted by TP#1, TP#2 and TP#3 in 2020, 2021 and to 06/07/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, signed and dated by the Laboratory Director on 6/07/2022, found two individuals credentialed and listed as TC's. 2. Review of the laboratory's education documentation for TC#2 revealed TC#2 achieved a Bachelor of Science in Health Care Services, Forensic Science. 3. The inspector requested TC#2's transcripts and other education documentation showing that TC#2 met the TC qualification requirements. TC#1 provided TC#2's transcripts on 06/08/2022 at 12:56 PM which were reviewed and determined that TC#2 did not meet the minimum TC requirement according to CFR 493.1411(b)(4)(i). 4. The Inspector notified TC#1 in an electronic mail (email) on 06/08/2022 at 4:34 PM that TC#2 did not meet the minimum requirement according to CFR 493.1411(b)(4)(i).

**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 record review and an interview with Technical Consultant (TC) #1, a qualified TC failed to assess the competencies of testing personnel (TP) #1, TP#2 and TP#3 in 2020, 2021 and 2022 assuring their competency was maintained in order to perform moderately complex hematology testing procedures and report the test results

promptly, accurately, and proficiently. All 200,075 moderately complex hematology testing procedures conducted by TP#1, TP#2 and TP#3 in 2020, 2021 and to 06/07/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "AON Clinical Laboratory Annual Competencies During COVID-19 Pandemic" policy and procedure, provided on the date of the inspection, found the following instructions for TP competency assessments: "During the COVID-19 pandemic and at the discretion of Federal and State travel recommendations AON will temporarily allow the Clinic Lead MA or MLT to perform direct observations as part of the annual competencies on the lab staff...Once travel restrictions are lifted, the Quality Assurance Supervisor will resume performing the direct observations as part of the competencies." 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 06/07/2022, revealed three TP listed and credentialed to perform moderately complex hematology testing procedures. 3. Review of the laboratory's 2020, 2021 and 2022 competency assessment records revealed the unqualified TC#2 assessed the competency of TP#1, TP#2 and TP#3 and not by a qualified TC. TC#1 confirmed on 06/08/2022 at 4:34 PM, that the laboratory's 2020, 2021 and 2022 competency assessments were not completed as required.