

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D1107381	<b>(X3) Date Survey Completed</b>  10/12/2022
<b>Name of Provider or Supplier</b>  Avalon Medical Clinic Llc	<b>Street Address, City, State</b>  1413 W Quitman Street, Iuka, MS	
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 review of the CMS (Centers for Medicare and Medicaid Services) 209 personnel form, lack of qualifying documentation, and interview with testing personnel (TP) #2/office manager at 2:30 p.m. on 1/12/2022, the laboratory did not have a technical consultant who meets the qualification requirements of 493.1411 of this subpart.</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 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</p>

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 review of the CMS 209 personnel form, lack of qualifying documentation available for review and interview with the TP #2/office manager at 2:30 p.m. on 10/12/2022, the laboratory did not have an individual designated as technical consultant who meets the qualification requirements of 493.1411 of this subpart from 3/1/2022 through 10/12/2022.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
 CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory testing records from 1/3/2022 through 10/12/2022 and interview with TP #2/office manager at 3:30 p.m. on 10/12/2022, the following records had not been documented as reviewed by a qualified technical consultant (TC): Findings Include: 1. Surveyor review of temperature records, quality control reports, proficiency testing reports, and Sysmex XP-300 calibration records from 1/3/2022 through 10/12/2022 revealed the following records had not been documented as reviewed by a qualified technical consultant: a. Temperature logs (room, freezer, humidity, and refrigerator) from 1/11/2022 through 10/12/2022 b. Sysmex XP-300 quality control (QC) from 1/11/22 through 10/12/22 c. Proficiency Testing results for the 1st and 2nd events of 2022 d. Sysmex XP-300 calibration documents for 12/3/2021 (installation) and 6/23/2022 2. Interview with TP #2/Office manager at 3:30 p.m. on 10/12/2022 confirmed there was no documented review of these records by a qualified TC.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
 CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of testing personnel records including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with TP #2 /office manager at 4:00 p.m. on 10/12/2022, a qualified technical consultant failed to evaluate semiannually and document the performance of TP #1, #2 and #3 who are responsible for performing moderate laboratory testing. Findings include: 1. The surveyor reviewed laboratory personnel records including the CMS 209 form available on 10/12/22. TP #1 training date 12/23/2021 - no 6 month competency evaluation which was due in June 2022 TP #2 training date 2/8/2022 - no 6 month competency evaluation which was due in August 2022 TP #3 training date 2/8/2022 - no 6 month competency evaluation which was due in August 2022 2. Interview with TP #2/office manager confirmed at 4:00 p.m. that TP #1, TP #2 and TP #3 had no documented 6 month competency evaluations by a qualified TC during their first year of moderate complexity testing.