

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0665664	(X3) Date Survey Completed 05/21/2025
Name of Provider or Supplier Associated Medical Specialists, Pa DbA	Street Address, City, State 8121 Rourke Street, Myrtle Beach, SC	
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
D0000	An announced onsite CLIA recertification survey was conducted on May 21, 2025, at the laboratory of Coastal Cancer Center of Myrtle Beach by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a list of Standard Level deficiencies cited as a result of the May 21, 2025 recertification survey:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on records review, CMS 209 form, and staff interview, the laboratory failed to rotate chemistry proficiency testing (PT) among testing personnel (TP). Findings included: 1. Review of the CMS 209 form for the survey conducted on May 21, 2025 lists 19 TP. 2. Review of American Proficiency Institute (API) Attestation statement documentation reveals: TP1 is listed as testing personnel for the following PT events: 2024 Chemistry 1st event 1/24/24 2024 Chemistry 2nd event 5/30/24 2024 Chemistry 3rd event 9/10/2024 2025 Chemistry 1st event 1/21/2025 2024 Immunology 1st event 3/28/2024 2024 Immunology 2nd event 8/1/2024 2025 Immunology 1st event 4/1/2025 2024 Hematology 1st event 3/8/2024 2024 Hematology 2nd event 7/22/2024 2024 Hematology 3rd event 11/8/2024 2025 Hematology 1st event 3/14/2025 3. The above documentation reveals the laboratory's failure to rotate PT testing to TP that routinely perform testing. 4. In an interview with TP1 on May 21, 2025 at 1:00pm in the laboratory, the findings were confirmed.</p>

<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to follow its policy and procedure for an ongoing process to monitor , assess, and when indicated, correct problems identified by quality assessments. Findings included: 1. Review of laboratory documentation reveals a lack of quality assessment activities. 2. Review of the laboratory's "QA Statement and Additional QA Measures" indicates QA audits are to be performed "quarterly". No quarterly documentation was available for review. 3. In an interview on May 21, 2025 at 1:00pm in the laboratory conference room with the Technical Supervisor (TS), the findings were confirmed.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on records review, manufacturer's instructions, observation, and staff interview, the laboratory failed to ensure materials used in patient testing were being stored as required. Findings included: 1. Review of temperature and humidity logs reveals a lack of documentation for the blood drawing room and storage room. 2. Vacutainer collection tubes were observed in the storage room with manufacturer's storage temperature of 4-25 degrees C. The tubes included: a. 36 flats of lavender top collection tubes 4ml K3EDTA, lot # 24103M, expiration date 01/31/2026. b. 1 flat of green top collection tubes sodium heparin, lot #B240936K, expiration date 01/31/2026. 3. Surveyor observed that there was no temperature monitoring device in the storage room or the blood drawing room. 4. In a staff interview on May 21, 2025, at 2:51pm in the storage room with TP1, the findings were confirmed.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on records review, manufacturer's instruction, and staff interview, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings included: 1. Review of the Vitros 5600 maintenance log reveals the following: a. Lack of documentation for monthly maintenance for January 2023, June 2023, and December 2023. b. Lack of documentation for quarterly maintenance for April 2023, August 2023, and December 2023. 2. In an interview with TP1 on May 21, 2025 at 1:40pm in the laboratory, the findings were confirmed.