

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D1013798	<b>(X3) Date Survey Completed</b> 08/16/2024
<b>Name of Provider or Supplier</b> North Myrtle Beach Internal Medicine	<b>Street Address, City, State</b> 8203 Nigels Drive Suite 201, Myrtle Beach, SC	
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>D0000</b>	An onsite announced CLIA recertification survey was performed on August 16, 2024 at North Myrtle Beach Internal Medicine's clinical laboratory by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a description of the Standard Level deficiencies cited:
<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 laboratory document review and staff interview, the laboratory failed to follow its own policy and procedure for personnel competency assessments. Findings included: 1. From the laboratory's policy entitled "Quality Assurance Monitors", "Twice during the first year and annually thereafter, the Director or his/her designee will evaluate the competency of all testing personnel to determine whether further training or retraining is required". 2. Review of personnel competency records revealed no initial or 6 months competency evaluations for any of the current personnel. Only annual competency evaluations were available for review. 3. In an interview with testing personnel #1 on August 16, 2024 in the laboratory office at 1:30 pm, the above findings were confirmed.</p>
<b>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on laboratory policy and procedure, laboratory documentation, and staff interview, the laboratory director failed to ensure that initial and 6 month competency assessments for 2 of 2 testing personnel was performed. Findings included: 1. From the laboratory's policy entitled "Quality Assurance Monitors", " Twice during the first year and annually thereafter, the Director or his/her designee will evaluate the competency of all testing personnel to determine whether further training or retraining is required". 2. Lack of documentation for initial and 6 month personnel competency evaluations for 2 out of 2 testing personnel. 3. In an staff interview with TP1 on August 16, 2024 in the laboratory office at 1:30 pm, the above findings were confirmed.