

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2158126	(X3) Date Survey Completed 09/11/2024
Name of Provider or Supplier Grand Strand Pediatrics & Adolescent Medicine, Pa	Street Address, City, State 5015 Carolina Forest Blvd, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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 the College of American Pathologists (CAP) Proficiency Testing (PT) records, the Laboratory Personnel Report (CMS-209), and interview with laboratory staff (TP-1 and TP-2), the laboratory failed to ensure five of six testing personnel (TP) who routinely performed patient testing participated in PT sample testing during the years of 2022, 2023, and 2024. Findings include: 1. The laboratory's CMS-209 lists six TP performing Cell Blood Count (CBC) analysis. 2. The laboratory participated in 8 CAP-PT events during the years of 2022 through 2024. The PT documents revealed since event 3 of 2022 six of six attestation statements for PT sample testing were signed by the same TP (TP-2). 3. On September 11, 2024 at 10:07 am, the surveyor asked TP-1 and TP-2 if all of the testing personnel who perform CBC testing participated in proficiency testing. Both replied that only TP-2 participated in all the PT events. 4. On a Recertification survey conducted on 9/11/2024 at 11:30 AM, the laboratory staff (TP-1 and TP-2) confirmed the above findings.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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>

This STANDARD is not met as evidenced by:

Based on the Laboratory Personnel Report (CMS 209), employee records, lack of documentation, and interviews with laboratory staff (TP-1 and ST-A), the laboratory failed to establish and follow written policies and procedures to assess employees performing the Cell Blood Count (CBC) for six of six testing personnel (TP) during the years of 2023 and 2024. Findings include: 1. The employee records and the Laboratory Personnel Report (CMS 209) were reviewed. 2. CMS 209 listed six TP (TP1, TP2, TP3, TP5, TP7, and TP8) performing CBC testing. 3. The employee records revealed the last competencies performed for each TP to be the following: TP-1 - 9/12/2022; TP-2 - 9/12/2022; TP-3 - 1/12/2023; TP-5 - 9/12/2022; TP-7 - 9/12/2022; and TP-8 - 1/12/2023. 4. Further review of the employee records and the laboratory's policies and procedures showed that the laboratory failed to establish a step-by-step procedure that includes the following criteria to assess TP competency for CBC testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing, as applicable; b). Monitoring the recording and reporting of test results (for example, recording patients and their results in the labs' test log and EMR system); c). Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d). Direct observation of performance of instrument maintenance and function checks; e). Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; f). Assessment of problem solving skills; and g). Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually. 5. On a Recertification survey conducted on 09/11/2024 at 10:15 AM, ST-A and TP-1 confirmed the above findings.