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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 42D0251969 | (X3) Date Survey Completed 05/15/2025 |
| Name of Provider or Supplier Strand Gi Associates | Street Address, City, State 7900 N Kings Hwy, 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 |
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| D0000 | An onsite recertification survey was conducted at Strand GI Associates in Myrtle Beach by South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services on May 15, 2025. The facility was found to be out of compliance with the Medicare condition at 42 CFR part 493 Laboratory Requirements. The following is a list of deficiencies cited as a result of the recertification CLIA survey on May 15, 2025. |
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation lack of documentation and staff interview, the laboratory failed to establish and verify performance of ventilation hood. Findings included: 1. During a tour of the laboratory, on May 15, 2025, at 3:45 pm the surveyor directly observed a fume hood. The Protector XVS Ventilation Station by Labconco did not have a maintenance sticker on it. 2. Review of the laboratory's environmental records reveal a lack of documentation for maintenance on the ventilation station used for processing patient specimens. 3. In an interview on May 15, 2025, at 3:45 pm in the laboratory with testing personnel, the above findings were confirmed.</p> |