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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 42D0942418 | (X3) Date Survey Completed 03/30/2026 |
| Name of Provider or Supplier Palmetto Digestive Disease, Pa | Street Address, City, State 2073 Charlie Hall Blvd, Charleston, 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 announced onsite CLIA recertification survey was conducted on March 30, 2026, at the laboratory of Palmetto Digestive Disease PA 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 standard level deficiency was cited: |
| D5391 | <p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>(a) 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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on records review, documentation, and staff interview, the laboratory failed to have an ongoing mechanism to biannually assess quality and audit the accuracy of results entered into the laboratory information system (LIS). Findings Included: 1. Review of the laboratory's QA plan revealed there was no policy for at least twice per year auditing of the accuracy of data uploaded into the LIS. 2. No documentation was available for review of the validation studies performed for the LIS at the time of the survey. 3. In an interview with the TS (technical supervisor) on March 30, 2026 at 1:00pm in the laboratory office, the findings were confirmed.</p> |