

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0252960	(X3) Date Survey Completed 12/10/2025
Name of Provider or Supplier Digestive Disease Group Pa	Street Address, City, State 103 Liner Drive, Greenwood, 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 December 10, 2025, at the laboratory of Digestive Disease Group of Greenwood 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, Requirements for Laboratories. The following is a list of Standard level deficiencies cited as a result of the December 10, 2025, recertification survey.
D5291	<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, QA/QC plan review, and staff interview, the laboratory failed to perform twice annually LIS verification. Findings included: 1. Review of laboratory records of QA activities reveals a lack of documentation for twice annual LIS verification. 2. Review of the laboratory's policy and procedure manual reveals a lack of reference to the performance of twice annual QA activities. 3. In an interview on December 10, 2025 at 1:00pm in the laboratory office with the LD, TP1, TP2, and TP3, the findings were confirmed.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and</p>

complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on records review, competency testing procedure, and staff interview, the laboratory director failed to ensure that prior to patient testing that all personnel have appropriate training and have demonstrated that they can perform all testing operations reliably. Findings included: 1. Review of the laboratory's Competency Testing procedure reveals the requirement for evaluation at 6 months and 1 year for new employees. 2. Review of the competency testing procedure reveals a lack of requirement for initial competency evaluation of new employees. 3. In an interview on December 10, 2025 at 1:00pm in the laboratory office with the LD, TP1, TP2, and TP3, the findings were confirmed.