

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2238486	<b>(X3) Date Survey Completed</b>  05/22/2024
<b>Name of Provider or Supplier</b>  Peak Gastroenterology Associates, Inc	<b>Street Address, City, State</b>  3495 Hacks Cross Road, Suite 102, Memphis, TN	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, and staff interview, the laboratory failed to follow its policy for reagent labeling for two of two marking dyes observed on the day of the survey. 1. Observation of the laboratory on 05/22/24 at 8:15 a.m. revealed equipment, reagents, and stains used for processing and grossing patient surgical tissue. The blue and green marking dyes were not labeled with lot number or storage requirements. 2. A review of the laboratory's procedure manual revealed the following: "All containers of reagents, calibrators, controls, and solutions, either in their original containers or aliquoted in a new container, must include the following on the label affixed to the container or recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified are identified so they are traceable to the appropriate data in the log: a. Chemical name and strength, concentration or titer b. Lot number of the original material if aliquoted c. Date aliquoted d. Initials of the person that aliquoted the reagent e. Expiration date assigned by the manufacturer or assigning expiration dates section of the procedure f. Storage requirements g. The NFPA diamond or Global Harmonize System (GHS) labels indicating the hazards associated with the materials 3. The general supervisor confirmed the laboratory failed to follow its policy for reagent labeling during interview on 05/22/24 at 12:05 p.m.</p>