

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0982971	<b>(X3) Date Survey Completed</b>  01/23/2024
<b>Name of Provider or Supplier</b>  Louisiana Gastroenterology Associates, Llc	<b>Street Address, City, State</b>  1211 Coolidge Blvd, Suite 303, Lafayette, LA	
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>D0000</b>	A Recertification survey was conducted on January 23, 2024 at Louisiana Gastroenterology Associates, LLC, CLIA ID # 19D0982971. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's temperature records, and interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the laboratory. Findings: 1. Observation by surveyor during the laboratory tour on January 23, 2024 at 10:45 a.m. revealed the following reagents stored in the laboratory: - Histology Connections - HC Ascertain Bluing Buffer, RTU - manufacturer's storage requirements 15-30 degrees Celsius - Histology Connections - HC Ascertain Clarifying 2 Reagent (RTU) - manufacturer's storage requirements 15-30 degrees Celsius - Histology Connections - Differential Rapid Blood Stain, Solution A - manufacturer's storage requirements 15-30 degrees Celsius - Histology Connections - Differential Rapid Blood Stain, Solution B - manufacturer's storage requirements 15-30 degrees Celsius - Histology Connections - Schiff Stain Solution, McManus - manufacturer's storage requirements 15-30 degrees Celsius - Histology Connections -</p>

Periodic Acid Solution, 1.0% w/v - manufacturer's storage requirements 15-30 degrees Celsius - Histology Connections - Alcian Blue Stain Solution, 1% w/v, pH 2.5 - manufacturer's storage requirements 15-30 degrees Celsius 2. Review of the laboratory's temperature records revealed the laboratory defined the acceptable limits for room temperature as 55-80 degrees Fahrenheit which the surveyor calculated to equal 12.8 - 26.7 degrees Celsius. 3. In interview on January 23, 2024 at 12:36 p.m., the Laboratory Director confirmed the laboratory's acceptable room temperature limits exceeded the manufacturer's acceptable limits for room temperature.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on observation, review of manufacturer's package inserts, and interview with personnel, the laboratory failed to establish and label expiration dates for marking dyes. Findings: 1. Observation by surveyor during the laboratory tour on January 23, 2024 at 10:45 a.m. revealed the following open and in use marking dyes in their original primary containers: - TMD Tissue Marking Dye - Cat #TMD7 (blue), quantity: one (1) bottle - TMD Tissue Marking Dye - Cat #TMD7 (green), quantity: one (1) bottle - TMD Tissue Marking Dye - Cat #TMD7 (black), quantity: one (1) bottle - TMD Tissue Marking Dye - Cat #TMD7 (red), quantity: one (1) bottle 2. Further observation revealed the marking dye bottles identified above did not have expiration dates marked on each container. 3. Review of the manufacturer's package inserts for the marking dyes revealed the manufacturer did not define an expiration date for the dyes. 4. In interview on January 23, 2024 at 11:00 a.m., the Laboratory Director confirmed the laboratory did not establish an expiration date for the marking dyes identified above or label them with an expiration date.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on observation, review of maintenance records, and interview with personnel, the laboratory failed to perform and document maintenance on the microtome as required by the laboratory for twenty (20) of twenty (20) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on January 23, 2024 at 10:45 a. m. revealed the laboratory utilized two (2) microtomes: a) Shandon Finesse ME + b)

Leica RM2235 2. Review of the laboratory's maintenance logs revealed the following: "Microtome oiled on: \_\_\_\_\_ \*\*Per manufacturer's manual microtome should be oiled monthly\*\*" 3. Further review of the laboratory's maintenance logs from May 2022 through December 2023 revealed the laboratory did not document oiling the microtome each month from May 2022 through December 2023. 4. In interviews on January 23, 2024 at 12:36 p.m., Testing Personnel 1 stated that the microtome maintenance is performed on the first of every month but was not documented. The Laboratory Director confirmed the maintenance identified above was not documented from May 2022 through December 2023.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the laboratory. Refer to D5413. 2. The laboratory failed to establish and label marking dyes in primary containers with expiration dates for proper use. Refer to D5415.

**D6095**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:  
Based on observation, review of maintenance logs, and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were performed to ensure acceptable levels of test performance. Refer to D5433.