

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2034794	<b>(X3) Date Survey Completed</b>  05/17/2022
<b>Name of Provider or Supplier</b>  Acadiana Gastroenterology Associates	<b>Street Address, City, State</b>  439 Heyman Blvd, 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 performed on May 17, 2022 at Acadiana Gastroenterology Associates, LLC, CLIA ID # 19D2034794. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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 review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to define the acceptable temperature limits for the embedding center. Findings: 1. Review of the laboratory's "Instrument and Equipment Maintenance and Schedules/Uses and QC" policy under the "Embedding Center: Dispenser and Cold Plate" section revealed the following: "The temperatures are as follows: Hot Plate range is 58-68 degrees Celsius. Cold Plate range is -6 to -14 degrees Celsius. Paraffin holding tank is 58-68 degrees Celsius." 2. Review of the laboratory's temperature logs for the "Embedding Center Paraffin" revealed the following temperature requirements that did not match the laboratory's policy: a) "Paraffin Reservoir 69 -2 C" b) "Cold plate 5 C" c) "Cassette bath 69 -+2 C" d) "Work surface 69 +-3 C" 3. In interview on May 17, 2022 at 12:30 pm, the Testing Personnel confirmed the laboratory's policy did not match the temperature logs. The Testing Personnel stated the laboratory needed to update their policies.</p>

<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure stains did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on May 17, 2022 at 11:26 am revealed the following expired item: HP Blue Stain, Lot 6917, Expiration Date: 2022-01-11, Quantity: one (1) bottle 2. In interview on May 17, 2022 at 11:40 am the Testing Personnel stated she thought the identified HP Blue stain expired in November, not January. The Testing Personnel confirmed the identified stain was expired.</p>
<p><b>D5433</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to establish and document maintenance procedures for the microscope utilized for Histopathology testing. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for microscope maintenance. 2. In interview on May 17, 2022 at 1:30 pm, the Testing Personnel stated she developed a maintenance log for the microscope that was not in use at the time of the survey.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, 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 the acceptable temperature limits for the embedding center. Refer to D5413. 2. The laboratory failed to ensure stains did not exceed expiration dates. Refer to D5417.</p>
<p><b>D6095</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b></p>

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 review of records and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were established and maintained to ensure acceptable levels of test performance. Refer to D5433.