

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2034794	<b>(X3) Date Survey Completed</b>  01/28/2020
<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 Certification Survey was performed on January 28, 2020 at Acadiana Gastroenterology Assocites, LLC, CLIA ID # 19D2034794. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range per laboratory policy. Findings: 1. Review of the laboratory's "Temperature and Humidity Monitoring for Histology" policy revealed "Refer to charts and log values on each instrument. If the values fall outside of range make adjustments and document the changes made at the bottom of chart. Initial and date all comments. Laboratory temperature: range 20-28C or 68-82F." 2. Review of the laboratory's "Temperature/Humidity Logs" for 2018, 2019, and January 1, 2020 through January 27, 2020 revealed the room temperature was documented as outside of the acceptable limits without documented corrective actions for the following twenty eight (28) days: November 4, 2019 documented room temperature 66 degrees</p>

Fahrenheit November 5, 2019 documented room temperature 66 degrees Fahrenheit November 6, 2019 documented room temperature 66 degrees Fahrenheit November 7, 2019 documented room temperature 66 degrees Fahrenheit November 8, 2019 documented room temperature 66 degrees Fahrenheit November 12, 2019 documented room temperature 64 degrees Fahrenheit November 13, 2019 documented room temperature 64 degrees Fahrenheit November 14, 2019 documented room temperature 66 degrees Fahrenheit November 15, 2019 documented room temperature 66 degrees Fahrenheit November 18, 2019 documented room temperature 66 degrees Fahrenheit November 25, 2019 documented room temperature 66 degrees Fahrenheit November 26, 2019 documented room temperature 66 degrees Fahrenheit November 27, 2019 documented room temperature 66 degrees Fahrenheit December 2, 2019 documented room temperature 66 degrees Fahrenheit December 3, 2019 documented room temperature 66 degrees Fahrenheit December 4, 2019 documented room temperature 66 degrees Fahrenheit December 5, 2019 documented room temperature 66 degrees Fahrenheit December 6, 2019 documented room temperature 66 degrees Fahrenheit January 6, 2020 documented room temperature 66 degrees Fahrenheit January 7, 2020 documented room temperature 66 degrees Fahrenheit January 8, 2020 documented room temperature 66 degrees Fahrenheit January 9, 2020 documented room temperature 66 degrees Fahrenheit January 10, 2020 documented room temperature 66 degrees Fahrenheit January 13, 2020 documented room temperature 66 degrees Fahrenheit January 20, 2020 documented room temperature 66 degrees Fahrenheit January 22, 2020 documented room temperature 66 degrees Fahrenheit January 23, 2020 documented room temperature 66 degrees Fahrenheit January 24, 2020 documented room temperature 66 degrees Fahrenheit 3. In interview on January 28, 2020, the General Supervisor confirmed the laboratory did not perform corrective action for the identified dates.

**D6096**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(7)

The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.