

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2152805	<b>(X3) Date Survey Completed</b>  12/19/2019
<b>Name of Provider or Supplier</b>  Acadian Diagnostic Laboratories Llc	<b>Street Address, City, State</b>  2429 Manatee Avenue #4, Bradenton, FL	
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>	An unannounced complaint survey, #2019018000, was conducted on 12/19/19 at Acadian Diagnostic Laboratories LLC. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories.
<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 record review, observation, and interview with the Technical Consultant the laboratory failed to record refrigerator and freezer temperatures where controls and calibrators are stored and room temperature and humidity since 12/13/19. Findings Included: Review of temperature logs revealed that all refrigerator and freezer temperatures had not been recorded since 12/13/19. Observations revealed that there were controls in the refrigerator and calibrators in the freezer. Review of temperature logs revealed that the room temperature and humidity had not been recorded since 12/13/19. Interview on 12/19/19 at 6:15 PM via telephone, the Technical Consultant confirmed patient testing was being performed and that the logs were not completed.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review, observation, and interview with the Technical Consultant the laboratory failed to record daily maintenance on the Sysmex XN 550 Hematology analyzer since 12/13/19. Findings Included: Review of maintenance logs revealed that daily maintenance had not been documented since 12/13/19. Daily maintenance consists of printing background, quality controls, and shutdown. Interview on 12/19/19 at 6:15 PM via telephone, the Technical Consultant confirmed patient testing was being performed and that the logs were not completed.

**D5441**

**CONTROL PROCEDURES**

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, observation, and interview with the Technical Consultant the laboratory failed to provide the daily quality control for November and December of 2019 for the Sysmex Hematology analyzer. Findings Included: Review of daily quality control logs revealed no logs for November and December of 2019. Interview on 12/19/19 at 6:15 PM via telephone, the Technical Consultant confirmed patient testing was being performed and the quality control could not be printed or pulled until someone was onsite to do it and that could not be done during the time of the survey.