Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2295058	09/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Acadian Health, Llc	937 15th Place, Vero Beach, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial certification survey was conducted on August 26, 2024 to September 10, 2024. Acadian Health LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to document the room temperature and humidity where the EPOC test cartridges for the EPOC Blood Analyzer were stored from 01/08/20224 to 08/26/2024. Findings: Review of the EPOC test cartridges showed, the cards storage temperature range was 15 to 30 degrees Celsius. No temperature and humidity logs were available for review. On 08 /26/2024 at 4:25 AM, Testing Personnel KK acknowledged the temperature and humidity of the room where the cartridges were stored was not recorded.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of Quality Controls (QC), patient records, and interview, the laboratory ran one of one patient sample when one of two levels of controls (L1, L2) was out between July 18, 2024 and July 27, 2024. Findings: Review of the QC records for the EPOC Blood Analyzer serial number RDR49895 showed on July 18, 2024, L1 was run three times at 7:33 AM, 11:35 AM, and 11:41 AM, and failed all three times. Review of the QC records showed L1 did not pass until July 27, 2024 AT 6:09 AM. Review of the patient record for the EPOC Blood Analyzer serial number RDR49855 showed one patient's sample was run on July 24, 2024 at 3:05 PM. On 08/26/2024 a 4:00 PM, Testing Personnel H, acknowledged one patient was run when the QC was out.