Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D1013827	**(X3) Date Survey Completed** 03/29/2023
Name of Provider or Supplier Brian G Fabian Md Pa	**Street Address, City, State** 26800 S Tamiami Trl Ste 390, Bonita Springs, 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 announced CLIA recertification survey was conducted at Brian G Fabian MD PA on 03/29/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 review of manufacturer's instructions, lack of documentation, and interview with the Practice Manager, the laboratory failed to document the room temperature to ensure the correct operating conditions for the cryostat for two out of two years review (2021 - 2023). Findings included: Review of the manufacturer's instructions for the cryostat revealed "Operating temperature range (ambient temperature): 18 degrees Celsius to 40 degrees Celsius." No documentation of room temperature from January 15, 2021 to March 29, 2023 could be provided. On 03/29/23 at 12:00 p.m., the Practice Manager stated the laboratory monitored the room temperature but did not document the room temperature on a log. .