

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1084550	<b>(X3) Date Survey Completed</b>  03/07/2022
<b>Name of Provider or Supplier</b>  Cynthia Rogers Md Pa	<b>Street Address, City, State</b>  8503 S Us 1 Ste 9, Port Saint Lucie, 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>	A recertification survey was conducted on March 7, 2022. Cynthia Rogers MD PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<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 record review and interview, the laboratory failed to record the room temperature and humidity of rooms where testing was performed from 03/07/2020 to 03/07/2022. Findings: Review of the Instructions for Use manual for the laboratory's Leica CM1520 Cryostat noted room temperatures should be between 18 - 35 degrees Celsius and maximum humidity of the room should be 60% (percent). A review of the laboratory's logs showed the laboratory failed to record the room temperature and the humidity of the room where testing was performed. During an interview 03/07/2022 at 3:02 PM, the Practice Manager stated they did not record the room temperature nor the humidity of the laboratory.</p>