

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0979214	<b>(X3) Date Survey Completed</b>  09/17/2018
<b>Name of Provider or Supplier</b>  Russel S Glaun Md Pa	<b>Street Address, City, State</b>  1590 Nw 10th Ave Ste 304, Boca Raton, 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>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 and interview with the laboratory director, the laboratory failed to document the room temperature and humidity from 2016 to 2018. Findings include: Review of the cryostat manual Leica CM1850 indicated a requirement for room temperature with a operational range of 18 C to 40 C and humidity lower than 60 %. Quality control records of laboratory room revealed that there is no documentation of the humidity neither room temperature done from 2016 to 2018 During an interview on 09/17/18 at 12:00 p.m., the laboratory director confirmed that there was no record of room temperature or humidity for the period of reference.</p>