

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2040746	(X3) Date Survey Completed 06/15/2018
Name of Provider or Supplier Surgical Pathology Laboratories Pa	Street Address, City, State 6877 Sw 18th St Ste H201, Boca Raton, 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
D5413	<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 in 1 out of 7 days of use during 2017. Findings include: Review of the cryostat manual Leica CM1850 indicated a requirement for room temperature not greater than 35 C and humidity not above 60 %. Quality control records of histopathology room revealed that on June 10th , 2017 no documentation of the humidity neither room temperature done. During an interview on 06/15/18 at 12:00 p.m., the laboratory director confirmed that there was no record of room temperature or humidity for the day of reference.</p>