

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0885189	(X3) Date Survey Completed 08/02/2018
Name of Provider or Supplier Pathology Associates	Street Address, City, State 1600 Jenks Ave Suite 4, Panama City, 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	A recertification survey was conducted on August 2, 2018. Pathology Associates clinical laboratory had one deficiency found at the time of the visit.
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, it was determined that the laboratory did not document room temperature and humidity to assure optimal storage temperature for certain reagents and the cryostat machine for 2 years from August 2016 to 2018. Findings included: Review of the manufacturer's procedure indicated that the clearing solvent used for Histopath should be stored at a temperature between 15-30 degrees Celsius. The cryostat machine also requires humidity and room temperature for its optimal operation. There were no temperature and humidity logs available for documenting the temperature of the laboratory room. Interview on 08/02/18 at 1130 AM, testing person # 3 confirmed that the lab was not aware of the requirement to record humidity and room temperature and therefore it was not done and documented.</p>