

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0271087	(X3) Date Survey Completed 03/20/2018
Name of Provider or Supplier Pensacola Pediatrics Pa	Street Address, City, State 4951 Grande Dr, Pensacola, 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, it was determined that the laboratory did not document room temperature and humidity requirements to assure optimal operation temperatures of the Hematology Coulter analyzer for 2 years from March 2016 to March 2018. Findings included: Review of the manufacturer's procedure indicated that the Equipment Performance Parameter for Hematology Coulter AcT diff Analyzer operates at room temperature (16 degrees - 35 degrees Celsius or 61 degrees- 95 degrees Fahrenheit) at humidity no higher than 85% without condensation. There was no temperature log available for documenting the temperature of the laboratory room. Interview on 3/20/18 at 11:45 AM, testing person # M confirmed that the temperature and humidity of the laboratory room were not checked and documented.</p>