

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0271843	(X3) Date Survey Completed 02/21/2019
Name of Provider or Supplier Benton Pediatrics, Inc	Street Address, City, State 5612 Nw 43rd St, Gainesville, 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, the facility failed to monitor the humidity of the laboratory to ensure optimal operation of the hematology analyzer, Beckman Coulter Act Diff 2 for 2 out of 2 years (2017-2019) reviewed. Findings included: Review of the documents from February 2017 through February 2019, showed that there was no humidity recorded on the logbook. Interview on 2/21/19 at 10:45 AM, testing person # 4 confirmed that the laboratory was not aware of the requirements of the Coulter Act Diff 2 hematology analyzer to check and record the humidity daily.</p>