

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1054722	<b>(X3) Date Survey Completed</b>  10/18/2018
<b>Name of Provider or Supplier</b>  Coral Springs Holistic Pediatrics Llc	<b>Street Address, City, State</b>  9750 Nw 33rd St Ste 216, Coral Springs, 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 Hematology analyzer Drew 3 user manual review and interview with testing personnel (TP) # A, the laboratory failed to document room temperature and humidity requirement to assure optimal operation of the analyzer during 2016, 2017, 2018. Findings include: Review of the Drew 3 manual indicates that the operation temperature range is 18 to 32 C and humidity below 80 %. There was no log available for documenting the temperature and humidity of the laboratory room. During an interview on 10/18/2018 at 11:30 a.m., the TP # A confirmed that there was no documentation of room and humidity control check.</p>