

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0663184	(X3) Date Survey Completed 08/29/2018
Name of Provider or Supplier Physicians To Children Llc	Street Address, City, State 6920 Nervia St, Coral Gables, 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 Hematology analyzer Sysmex XP-300 user manual review and interview with Testing Personnel (TP), 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 Sysmex XP-300 manual indicates that the operation temperature range is 15 to 30 C and humidity range 30 to 85 %. There was no log available for documenting the temperature and humidity of the laboratory room. During an interview on 8/29/2018 at 10:30 a.m., the TPA confirmed that there was no documentation of room and humidity control check.</p>