Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0287315	09/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sawgrass Pediatric Partners Llc	9801 Glades Rd, Boca Raton, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with Nursing Supervisor (NS) the laboratory failed to do the annual competency evaluation for 6 (#A to #F) out of 22 testing personnel for 3 out 3 (2016-2018) years reviewed. Findings include: Review of employee competency documentation found no competency evaluations for testing person #A to #F for 2016 to 2018. During an interview on 9/17/2018 at 12:30 PM, with the NS, she confirmed that there were no competencies performed on the employees listed above for the years of reference.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on Hematology analyzer Medonic M series user manual review and interview

	with Nursing Manager (NM), 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 Medonic M series 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 9/20/2018 at 12:30 p.m., the NM confirmed that there was no documentation of room and humidity control check.