Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0723277	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Nicklaus Children's Pediatric Specialists, Llc	208 N University Dr, Pembroke Pines, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with Testing Personnel # A (TPA), the laboratory failed 1 out of 1 event for Bacteriology during the year 2018. Findings include: Review of API proficiency records revealed that the laboratory failed the Bacteriology first event of 2018 with a 0 % score. During an interview on 8/28/2018 at 11:30 AM, the TPA confirmed that the laboratory failed the event 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 Testing Personnel # A (TPA), 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 8/28/2018 at 12:30 p.m., the TPA confirmed that there was no documentation of room and humidity control check.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on calibration record review and interview with Testing Personnel # A (TPA), the laboratory failed to follow manufacturer instructions for the calibration process for one out of 3 years (2016-2018). Findings include: Review to the Medonic M series manual indicates to do the calibration at a minimum of every 6 months. Calibration record review showed the following calibration dates 3/11/2016, 7/28/2016, 9/25/2017, 12/21/2017, 3/20/2018, 5/16/2018 During an interview on 8/28/2018 at 12:30 p.m., the TPA confirmed that there was no record of calibration performed between 7/28/2016 to 9/25/2017.