Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D0723277	**(X3) Date Survey Completed** 05/13/2022
Name of Provider or Supplier Nicklaus Children's Pediatric Specialists, Llc	**Street Address, City, State** 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**
D0000	A recertification survey conducted on 05/10/2022 to 05/13/2022 found the SOUTH FLORIDA PEDIATRIC PARTNERS clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were cited: -D5002. Bacteriology. -D5400. Analytical Systems. -D6000. Moderate Complexity Laboratory Director.
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 record review and interview, the laboratory failed to score at least 80 % in Bacteriology for the second proficiency testing (PT) event in 2021. Findings include: Review of Bacteriology American Proficiency Institute (API) PT records for 2020, 2021 and first event of 2022 , revealed a 40 % score in the second event of 2021 resulting in a failing score for the subspecialty of Bacteriology. During an interview on 05/10/2022 at 12:25 PM, Testing Personnel #A confirmed that the laboratory failed to receive a passing score of at least 80 % for Bacteriology in the second event of 2021.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to keep, the

	instrument print outs with the results for proficiency testing (PT) samples for all testing events of 2020 and 2021 for the Hematology specialty and failed to keep the reading results documentation for the Bacteriology results for five out six events reviewed for 2020 and 2021. Findings include: Review of American Proficiency Institute (API) PT records for 2020 and 2021, revealed that the laboratory failed to have the print outs of Complete Blood Analyzer instrument corresponding to the PT samples for all events of each year for Hematology Specialty and for Bacteriology Specialty, for the test Selective Streptococcus Throat Culture the laboratory failed to have record of the reading of the results for the first, second event of 2020 and for the first, second and third event of 2021. During an interview on 05/13/2022 at 11:30 AM, Testing Personnel # A confirmed that the laboratory failed to have print outs and reading documentation for the events of reference.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory did not meet the Condition for Bacteriology from 02/28/2020 to 05/13/2022. Findings include: -Failed to have a Quality Control (QC) policy in place for the Selective Streptococcus Throat Culture (STC). Refer to D5403. -Failed to perform QC for each new lot number and shipment of the Bacitracin Discs used for the STC. Refer to D5471. -Failed to have documentation to indicate that they checked the physical characteristics of each culture media lot, or that they checked each culture media lot with control organisms as part of the QC for the STC. Refer to D5477. -The laboratory tested 297 patients without QC during this period of time.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory did not meet the condition for analytic systems. Findings include: -Failed to perform Medonic M Complete Blood Cell Analyzer instrument calibration at least every six months for 2020 and 2021. Refer to D5437. This is a repeated deficiency from the survey of 2018.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the procedure manual was incomplete for the Throat Culture procedure, it failed to include a Quality Control (QC) procedure for evaluation of the Selective Streptococcus Culture Media (STC) and the Bacitracin Discs and failed to include correct incubation time from 02/28/2020 to present Findings include: -Review of procedure manual signed by the laboratory director (LD) on 04/27/2022, revealed that the procedure failed to include a QC procedure for Culture Media to ensure that the laboratory checked and documented the physical characteristics of each lot of media and for Bacitracin Discs failed to describe the procedure to verify each new lot number and shipment and failed to include the correct incubation time of 18 to 24 hours as per Hardy Media manufacturer instructions. During an interview on 05/13/2022 at 1:30 PM, the Laboratory Director confirmed that the Procedure Manual failed to have a QC for the STC and failed to include the correct incubation time for the STC.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have documentation of the reading of Throat Cultures (TC) between 18-24 hours as per manufacturer instructions for 119 out of 297 patients from 02/28/2020 to 05/10/2022. Finding include: -Review of Throat Culture procedure revealed an incubation time instruction of 48 hours. -Review of Hardy Manufacturer Instruction revealed an incubation time of 18-24 hours. -Review of Bacteriology Patient Chart for TC for the years 2020, 2021 and 2022 revealed that the laboratory performed 297 tests and failed to have documentation of reading at 24 hours for 119 patients tested in this period. During an

	interview at 01:15 PM on 05/13/2022, the Laboratory Director explained that during the weekends he does the readings and he confirmed that he failed to do the documentation for the reading.
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 record review and staff interview, the laboratory failed to ensure the incubator temperature was in the range described in the Incubator General Policy from 02/27/2020 to present. The findings include: -Review of the Incubator general Information policy, revealed that the acceptable temperature range was from 35 to 37 degrees Celsius (C). -Review of Incubator Temperature Log revealed that the range listed on the Log was 24 to 38 C, which is outside the temperature described by the manufacturer of the culture media and the Incubator Policy. -Review of temperature records for 2020 (from 02/28/2020 to 12/31/2020); 2021 (01/01/2021 to 12/31/2021) and 2022 (01/01/2022 to 05/10/2022) revealed that the temperature was outside of the range established by the procedure manual in 167 days out of 536. During an interview at 01:30 PM on 05/10/2022, Testing Person #A confirmed that the Incubator temperature log was outside of the range and that the days of reference the temperature reading were outside the acceptable range.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to label complete blood cells controls currently in use with the new expiration date. Findings include: - During the laboratory tour on 05/10/2022 at 10:00 AM, the surveyor observed that the laboratory had in use Boule Con-Diff Tri Level Controls with Lot # 22201. The controls in use failed to have the opening date and the new expiration date. -Review of Medonic M series analyzer user manual, revealed on page 11, Section Quality Control that opened controls are stable for 14 days. During an interview on 05/10 /2022 at 10:35 AM, the Testing Personnel # A, confirmed that controls in use were not labeled as described above and she explained that she started using the current controls on 05/01/2022.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on Medonic M Series maintenance records and testing personnel (TP) A interview, the laboratory failed to document all required maintenance performed from 02/28/2022 to present. Findings include: Based on Medonic M Series analyzer user manual, the laboratory had to perform daily, weekly, monthly and semiannual maintenance actions. Review of the Maintenance log for 2020, 2021 and 2022, revealed that the laboratory failed to document the daily, weekly and monthly maintenance. During an interview on 05/10/2022 at 01:00 PM, the TP # A confirmed that there was no documentation of all required maintenance for the period of reference.
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 record review and staff interview, the laboratory failed to follow manufacturer instructions to do the calibration to the Medonic M Complete Blood Cell Analyzer at least every 6 months since 02/28/2020 to 05/10/2022. This is a repeated deficiency from the surver of 2018. Findings include: Review of the Medonic M series manual on page 7 of 11, on section CALIBRATION, Indicates to do the calibration at least every six months. Review of the Calibration records showed no calibration records for 2020, one on 01/13/2021 and another on 01/20/2022. During an interview on 05/10/2022 at 01:00 PM, Testing Personnel # A, explained that she could not find the records for other calibrations performed during this period of time.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or

	two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory failed to perform quality control (QC) on each new lot number and shipment of the Bacitracin Discs used for the Selective Streptococcus Throat Culture (STC) from 02/28/2020 to 05/13/2022. Findings include: -The laboratory had no records that support they have performed evaluation of each new lot number and shipment of the Bacitracin Discs used for the STC. -The laboratory tested 297 patients during the period of reference During an interview on 05/10/2022 at 12:30 PM, Testing Person # A confirmed that laboratory failed to perform Bacitracin Discs lot and shipment verification for the period of reference.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory failed to document the physical characteristics of the media from 02/28/2020 to 05/13/2022. Finding include: -Review of the Selective Streptococcus Throat Culture (STC) records revealed that there was no documentation of the physical characteristics of the media used for the STC since 02/28/2020 to present. -The laboratory tested 297 patients during the period of reference During an interview on 05/10/2022 at 12:35 PM, Testing Person # A confirmed that the physical characteristics of the media was not being documented.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory Quality Assurance (QA) failed to identify and correct the analytic deficiencies in the Throat Culture (TC) and the Complete Blood Cell (CBC) tests for 2 out of 2 years reviewed (2020, 2021) Findings include: -Failed to detect and correct the lack of Quality Control in the TC test. Refer to D5471 and D5477. -Failed to ensure that CBC analyzer calibration was done as per manufacturer instructions and or keep documentation, this is a repeated deficiency.

	Refer to D5437. -Failed to ensure incubator temperatures were set as stated in the procedure manual. Refer to D5413. -Failed to ensure the laboratory incubation time for the TC was according to manufacturer instructions. Refer to D5411 During an interview on 05/13/2022 at 1:35 PM, the Laboratory Director confirmed that the laboratory QA failed to correct the deficiencies listed above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to effectively oversee the laboratory from 02/28/2020 to 05/13/2022. Findings include: -Failed to ensure the laboratory performed Medonic M series complete blood counter calibrations every 6 months. Refer to D6013. This is a repeated deficiency. -Failed to ensure the laboratory reviewed proficiency testing results. Refer to D6018. -Failed to ensure the laboratory had a corrective action for a failure in proficiency testing. Refer to D6019. -Failed to ensure the laboratory had a quality control for Throat Culture and failed to ensure the quality assurance corrected the deficiencies. Refer to D6022.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and staff interview the Laboratory Director (LD) failed to ensure that the laboratory performed calibration of the Medonic M Complete Blood Cell Analyzer hematology analyzer at least every 6 months since 02/28/2020. Refer to D 5437.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and staff interview, the laboratory director (LD), failed to sign and review the results for 7 out of 7 events reviewed for the specialty of Hematology and Bacteriology (2020-2022). Finding include: Review of American Proficiency Institute (API) PT records revealed that the LD failed to review and sign the results for the first, second and third events of 2020 and 2021 and the first event of 2022 for the specialties of Hematology and Bacteriology. During an interview on 05/10/2022 at 12:30 PM, the testing personnel # A confirmed that the LD failed to sign the review of results of the events of reference.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and staff interview, there was no documentation to indicate that the Laboratory Director ensured that a corrective action was done when proficiency testing results were unsatisfactory for one event out of 7 events reviewed (2020 to 2022) The findings include: -Review of American Proficiency Institute (API) PT records for 2020, 2021 and first event of 2022, revealed a failure in the second event of Bacteriology. Refer to D2020. -No records found of a corrective action for this failure. During an interview on 05/10/2022 at 12:30 PM, testing personnel # A confirmed that the laboratory failed to have documentation of corrective action done for the failed PT result of reference.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure that quality control (QC) was performed for Throat Culture and failed to ensure the quality assurance (QA) corrected the analytic deficiencies in the Throat culture and the Complete Blood Cells Count. Findings include: Refer to: D5411, D5413, D5415, D5429, D5437, D5471, D5477 and D5791.