Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0723277	02/27/2020
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
D0000	A recertification survey conducted on 2-26-2020, found South Florida Pediatrics Partners clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 staff interview , the laboratory failed to establish and perform initial and six month competencies for 2 (TP#B and C) out of 4 testing personnel (TP) and annual competencies for 1 (TP#A) out of 4 TP , clinical consultant (CC) and technical consultant (TC) in 2019. Findings Include: A review of form CMS 209 Laboratory Personnel record displays that TP# A-D are testing personnel, CC#A is clinical consultant, and TC#A is a technical consultant . A review of Procedure Manual record revealed no personnel competency assessment policy . A review of 2019 Employee Competency Assessment record revealed that initial and six-month competencies were not performed for 2 (TP # B and C) out of 4 TP. Annual competencies was not performed for 1 (TP # A) out of 4 TP, CC # A and TC #A . During an interview on 2-27-2020 at 12:30 pm, The testing personnel A confirmed that initial and 6-month competency assessment were not done for two TP and the annual competency assessments were not performed for TP,CC and TC in 2019 .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide a quality assessment (QA) policy and preform QA monitoring and documentation for 2018-2019. Findings Include: A review of the Procedure Manual record revealed no policy for QA monitoring. A review of Strep Culture and Hematology Log record displayed no QA review for missing lot numbers, missing patient ID numbers and test expirations from 2018 to 2019. A review of Hematology Controls record displayed no QA review for Hematology controls from 2018 to 2019. During an Interview on 2-26-2020 at 12:30pm, the testing personnel A and laboratory manager confirmed that no QA policy and QA was not monitored and documentation for 2018 and 2019.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure proficiency testing enrollment for 1st out of 3 events in Hematology and Microbiology with the American proficiency institute (API) in 2019. Findings Include: A review of 2019 API Hematology Proficiency Testing record displayed missing evaluation scores for cell id, red blood cell count, hematocrit, hemoglobin, white blood cell count and platelets in 1st PT event of 2019. A review of 2019 API Microbiology Proficiency Testing record revealed missing bacteriology evaluation scores for strep throat culture in 1st PT event of 2019. During interview on 2-27-2020 at 12:30pm, the testing personnel A and laboratory manager confirmed failure to enroll in API 1st PT event for Hematology and Microbiology in 2019.