

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0708274	(X3) Date Survey Completed 10/04/2021
Name of Provider or Supplier Nicklaus Children's Pediatric Specialists, Llc	Street Address, City, State 11011 Sheridan St Ste 311, Cooper City, 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 09/28/2021-10/04/2021 found that the Atlantic Pediatric Partners clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to score at least an 80% in Bacteriology for the 2nd proficiency testing (PT) event in 2021. Findings included: Review of Bacteriology American Proficiency Institute record revealed the following scores for the 2nd PT event in 2021: 40% in Bacteriology 40% in Throat Culture During an interview on 09/28/2021 at 3:10 PM, the office manager confirmed the laboratory failed to receive a passing score of at least 80% in Bacteriology for the 2nd PT event in 2021.</p>
D2088	<p>ROUTINE CHEMISTRY CFR(s): 493.841(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to score at least an 80% in Routine Chemistry for the 2nd proficiency testing (PT) event in 2020. Findings included: Review of Routine Chemistry American Proficiency Institute record</p>

revealed the following scores for the 2nd PT event in 2020: 60% in Routine Chemistry 60% in Total Bilirubin During an interview on 09/28/2021 at 3:09 PM, the office manager confirmed the laboratory failed to receive a passing score of at least 80% in Routine Chemistry for the 2nd PT event in 2020.

D3000

FACILITY ADMINISTRATION
CFR(s): 493.1100

Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory failed to report 202 negative patient results for the COVID-19 Quickvue Sars-Antigen to the State of Florida from 05/17/2021 to 9/27/2021 Findings Included: Review of COVID-19 State of Florida ELR system revealed no documentation of COVID-19 negative patient results listed in the system for COVID-19 Quickvue Sars-Antigen testing. Review of patient records revealed 202 patients had been tested with the COVID-19 Quickvue Sars-Antigen and received a negative result for COVID-19 from 05/17/2021 to 9/27/2021. During an interview on 09/28/2021 at 3:11 PM, the laboratory manager and testing personnel confirmed that 202 negative COVID-19 patient results were not submitted to the state of Florida from 05/17/2021 to 9/27/2021.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and interview, the technical consultant failed to perform an initial competency assessment for 1 (TP#E) out of 5 testing personnel(TP). Findings Included: Review of Personnel Employee record revealed TP#E was a testing person hired in April 2021. Review of competency assessment records revealed that there was no documentation of an initial training competency assessment for TP#E in 2021. During an interview on 10/04/2021 at 10:21 AM, the office manager confirmed that there was no initial competency assessment for TP#E in 2021.