

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0708274	(X3) Date Survey Completed 10/03/2019
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 10/03/2019 found that the South Florida Pediatric Partners clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was cited: D6063- Laboratory testing Personnel
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209 Laboratory Personnel Report, review of American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel (TP) A. The laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the Chemistry and Microbiology specialty for 1 out of 2 years (2018 - 2019) reviewed. Findings include: Review of CMS 209 signed and dated by the Laboratory Director (LD) on 10/02/2019 had 4 testing personnel listed (TPA, TP B, TP C and TP D). Review of API PT records found that TP B, C and D did not perform PT in Chemistry Specialty during 2018 and TP C and D did not participate in PT for Microbiology during 2018. During an interview on 10/03/2019 at 11:30 AM, TP A confirmed that TP B, C and D missed to participate in PT during the year of above-reference</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the</p>

	<p>laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing (PT) records and interview with Testing Personnel # A (TPA), the laboratory failed to have an attestation signed for 1 out of 6 events reviewed (2017 3rd ; 2018 1st, 2nd and 3rd; 2019 1st and 2nd) for Chemistry and for 1 out of 6 events (2017 3rd ; 2018 1st, 2nd and 3rd; 2019 1st and 2nd) for Hematology Specialty reviewed . Findings include: Review of API proficiency records revealed that the laboratory failed to have a signed attestation for: -1st event of Hematology specialty of 2018 -3rd event of Chemistry specialty 2018 During an interview on 10/03/2019 at 11:30 AM, the TPA confirmed that the laboratory failed to have a signed attestation for the events of above-reference.</p>
<p>D2020</p>	<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 review of API (American Proficiency Institute) proficiency testing (PT) records and interview with Testing Personnel # A (TPA), the laboratory failed 1 out of 3 events for Bacteriology during 2018. Findings include: Review of API proficiency records revealed that the laboratory failed the Bacteriology first event of 2018 with a 60 % score. During an interview on 10/03/2019 at 11:30 AM, the TPA confirmed that the laboratory failed the event of reference.</p>
<p>D3011</p>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure that the testing personnel wear gloves during testing process. Findings include: Surveyor 2 observed that TP # B, manipulated a urine sample without using gloves, and after finishing the sample processing did not wash her hands on 10/03/2019 at 9:30 am. Surveyor 1 observed TP # B, performed a strep A+B test without wearing gloves and after that proceed to work with documentation without using any sanitation procedure on 10/03/2019 at 11:00 am. During an interview on 10/03/19 at 12:00 pm, TP # A, confirmed that TP # B, performed the procedures of reference without wearing gloves.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to document semi-annual competencies assessment for 2 out of 4 testing personnel (TP) (# A, B, C and D) in 2018 Findings include: - A review of CMS-209 laboratory personnel signed and dated on 10/02/2019 by laboratory director (LD) revealed that the laboratory had 4 TP. - Review of employee records revealed that TP # B started on July 2017, TP # C started on November 2017, no records of 6 months assessment documented. During an interview on 10/03/19 at 11:30 am, TP # A, confirmed there was no documentation of semi-annual competencies assessment for the TP's of reference.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on review of CMS form 209, a review of Testing Personnel (TP) files and interview with Office Manager (OM), the laboratory failed to verify proof of education in 1(#A) out of 4 (#A-D) TP (See D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review and interview with staff, the laboratory failed to verify proof of education in 1 (# A) out of 4 (#A-D) testing personnel (TP). Findings include: A review of CMS form 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 10/2/2019 revealed that there were 4 TP (TP # A-D). Review of TP files revealed that TP # A is a licensed practical nurse, but no proof of education was found. Without proof of education, the minimum education requirements could not be verified. During an interview on 10/3/2019 at 11:30 am with TP # A, she confirmed that she did not have proof of education, she state that she did her high school in a United Kingdom in 1963 and that she will contact them to obtain documentation.