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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0680711     | <b>(X3) Date Survey Completed</b><br><br>08/18/2020 |
| <b>Name of Provider or Supplier</b><br><br>Nicklaus Children's At Galloway   | <b>Street Address, City, State</b><br><br>7800 Sw 87th Ave Ste C350, Miami, FL |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
|---------------------------|---|
| <b>D0000</b>              | A recertification survey conducted on 8/18/2020 , found the South Florida Pediatrics Partners clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were cited : D5200- General Laboratory Systems  |
| <b>D3037</b>              | <p><b>RETENTION REQUIREMENTS</b><br/>CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and staff interview, the laboratory failed to keep American Academy of Family Physicians (AAFP) Hematology proficiency testing attestations for all 3 (1st, 2nd and 3rd) events in 2019 and 2 (1st and 2nd) out 3 events in 2020. Findings Include: Review of AAFP proficiency record revealed Hematology proficiency testing attestations were missing for 3 (1st, 2nd and 3rd) out of 3 events in 2019 and 2 (1st and 2nd) out 3 events in 2020. An interview on 8/18/2020 at 1:37pm, with the office manager confirmed AAFP proficiency testing attestations were missing for 3(1st, 2nd and 3rd) out of 3 events in 2019 and 2 (1st and 2nd) out 3 events in 2020.</p> |
| <b>D5200</b>              | <p><b>GENERAL LABORATORY SYSTEMS</b><br/>CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p>  |

This CONDITION is not met as evidenced by:  
Refer to D5209 : This is a repeat deficiency from 10-8-2018. The laboratory failed to perform and establish performance timeframes for 6-point competency assessment for testing personnel (TP). Refer to 5293: This is a repeat deficiency from 10-8-2018. The laboratory failed to document their monthly Quality Assurance Checklist for 10 out of 12 months in 2019 and 6 months in 2020.

**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:  
This is a repeat deficiency from 10-8-2018. Based on record review and staff interview, the laboratory failed to perform and establish performance timeframes for testing personnel (TP) competency assessments. Annual competency assessments were not performed for 3 (TP#A, TP#B, and TP#D) out of 4 TP in 2019 and 2020. Initial and 6-month competency assessments were not performed for 1 (TP#C) out of 4 TP in 2019. Findings Include: Review of the procedure manual revealed no documentation of timeframes for when competency assessment will be performed. Review of CMS -209 Laboratory Personnel Form confirmed that TP#A, TP#B, TP#C and TP#D are all TP. Review of Personnel Competency Assessment record showed TP#A, TP#B, and TP#D had no documentation of performed annual competency assessments for 2019 and 2020. TP#C had no documentation of performed initial and 6-month competency assessments. An interview on 8/18/2020 at 1:37pm, with the office manager confirmed annual, initial and 6-month competency assessments were not done for TP in 2019 and 2020.

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:  
This is a repeat deficiency from 10-8-2018. Based on record review and staff interview, the laboratory failed to document their monthly quality assurance for 10 (Jan-Feb, April -August and Oct-Dec.) out of 12 months in 2019 and 6 months (Jan.-Feb. and Apr.-July) in 2020. Findings Included: Review of Monthly Quality Assurance Checklist record revealed no documentation of monthly quality assurance for 10 months (Jan-Feb, April -August and Oct-Dec.) out of 12 months in 2019 and 6 months (Jan.-Feb. and Apr.-July) in 2020. An interview on 8/18/2020 at 1:37pm, with the office manager confirmed no documentation of quality assurance for 10 of 12 months in 2019 and 6 months in 2020.