

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0680711	<b>(X3) Date Survey Completed</b>  07/03/2024
<b>Name of Provider or Supplier</b>  Nicklaus Children's At Galloway	<b>Street Address, City, State</b>  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 07/03/2024 found the NICKLAUS CHILDREN'S PEDIATRIC SPECIALISTS, LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D2009</b>	<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 laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to sign attestation for Proficiency Testing for Hematology specialty for two out of two events reviewed. Findings included: Review of American Proficiency Institute (API) Proficiency Testing (PT) records for third event of 2023 and first event of 2024, revealed that the laboratory failed to have attestation signed for the events of reference for the Hematology Specialty tests: Erythrocyte count, Hematocrit, Hemoglobin, Leukocyte count, Platelet count, White Blood Cell Differential and Red Cell Distribution (RDW). During an interview on 07/03/2024 at 12:00 PM, the office manager confirmed that the laboratory failed to sign attestations for the events of reference.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p>

(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 observation, record review and staff interview, the laboratory failed to document room humidity and temperature requirement to ensure optimal operation for the Coulter Ac-T Diff 2 Analyzer for 2 out of 2 years reviewed. The findings included: An observation of laboratory on 07/03/2024 at 11:00 AM, indicated that no thermometer and humid meter located by the analyzer. A review of Coulter Ac-T diff2 Hematology Analyzer manual revealed a requirement for optimal operation a range of room temperature of 16 to 35 Celsius and Humidity between 20 to 85 %. A review of temperature logs for 2022 (September to December), 2023 and 2024 (January to June) revealed no documentation of room humidity and temperature. During an interview on 07/03/2024 at 1130 AM, the Office Manager confirmed that there was no documentation of the room temperature and humidity for the period of reference.

**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 interview with office manager, the laboratory director (LD) failed to assure that the facility enrolled in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for Hematology Specialty during the first and second event of 2023. Findings included: Review of American Proficiency Institute (API) PT records for 2023 revealed blank results in the first and second event of 2023. During an Interview on 07/20/2024 at 12.30 PM, the office manager confirmed that the LD failed to ensure the facility to enroll PT program for first and second events of 2023.