

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0708274	(X3) Date Survey Completed 12/12/2025
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	An announced CLIA recertification survey was conducted from 12/04/2025 to 12/12/2025 at NICKLAUS CHILDREN'S PEDIATRICS SPECIALISTS, LLC. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6000 493.1403 - Moderate Complexity Laboratory Director
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 staff interview, the laboratory failed to sign attestation for Proficiency Testing for for 1 out of 3 events reviewed in Chemistry and Hematology specialty in 2025. Findings included: 1. Review of American Proficiency Institute (API) Proficiency Testing (PT) records for 1st, 2nd and 3rd event for 2025, revealed that the laboratory failed to have attestation signed for Chemistry Core for the Neonatal Bilirubin test 3rd event and for the Hematology Specialty tests 3rd event: Erythrocyte count, Hematocrit, Hemoglobin, Leukocyte count, Platelet count, White Blood Cell Differential and Red Cell Distribution (RDW). 2. During an interview on 12/04/2025 at 12:00 PM, the Testing personnel #1 confirmed that the laboratory failed to sign attestations for the events of reference.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems</p>

activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to retain daily Quality Control (QC) records for Bilirubin control level 1 for 23 out of 23 testing dates from 05/27/2025 to 08/11/2025. Findings included: 1. Review of manufacturer instructions (MI) for Quantimetrix Bilirubin - Pediatric Level 1 & 2, revealed that the lot number for the batch in use since 04/04/2025 was 211431 for level 1 and 241432 for level 2. 2. Review of QC records for level 1 and 2, revealed that the laboratory had no records for level 1 for 25 patients tested the following dates: 05/27/2025 (2 patients tested), 05/29/2025 (1 patient tested), 05/30/2025 (1 patient tested), 06/01/2025 (1 patient tested), 06/08/2025 (1 patient tested), 06/11/2025 (1 patient tested), 06/12/2025 (1 patient tested), 06/13/2025 (1 patient tested), 06/15/2025 (1 patient tested), 06/16/2025 (1 patient tested), 06/17/2025 (1 patient tested), 06/18/2025 (1 patient tested), 06/19/2025 (1 patient tested), 06/22/2025 (1 patient tested), 06/26/2025 (1 patient tested), 06/30/2025 (1 patient tested), 07/01/2025 (1 patient tested), 07/07/2025 (1 patient tested), 07/14/2025 (1 patient tested), 07/22/2025 (1 patient tested), 07/27/2025 (1 patient tested), 07/29/2025 (1 patient tested), 08/05/2025 (1 patient tested) and 08/11/2025 (1 patient tested). 3. During an interview on 12/04/2025 at 1:35 PM, Testing Personnel #1 confirmed that the laboratory failed to have QC records for level 1 of Bilirubin for the period of 05/27/2024 to 08/11/2025.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to follow Manufacturer Instructions (MI) for daily and monthly maintenance of the Beckman Coulter Complete Blood Counter (CBC) DXH 500 during 2 out of 2 years reviewed. Findings included: 1. Review of the MI for CBC DXH 500, revealed that the user is required to do daily cleaning and monthly bleach cycle. 2. Review of DXH 500 Maintenance Checklist logs for 2024 and 2025 revealed the following: a) No documentation of the daily maintenance from 10/21/2024 to 10/25/2024, 04/14/2025 to 04/18/2025 and 10/08/2025 to 10/16/2025. b) No documentation of monthly bleach cycle on the following months: March 2024, April 2024, October 2024, January 2025, March 2025, May 2025, July 2025 and August 2025. 3. During an interview on 12/04/2025 at 11:13 AM, Testing Personnel #1 confirmed that the laboratory failed to follow MI for maintenance of CBC analyzer DXH 500 during 2024 and 2025.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	<p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to provide management of the laboratory's Proficiency Testing (PT) during 2025. Findings included: 1. The LD failed to ensure that the laboratory enrolled in PT during the first event of 2025 for Neonatal Bilirubin and Throat Culture tests. (See D6015).</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to ensure that the laboratory enrolled and participated in Proficiency Testing (PT) in the first event of 2025 for the Neonatal Bilirubin test and Throat Culture. Findings included: 1. Review of American Proficiency Institute (API) PT records for Chemistry (Neonatal Bilirubin) and Bacteriology (Throat Culture), revealed that the laboratory had no records for the 1st event of 2025. 2. Review of 2025 laboratory order revealed that the order was placed on 02/07/2025, and API notified the laboratory that they were not supplying the first event of Neonatal Bilirubin and no Throat Culture. 3. From 01/01/2025 to 04/30/2025 the laboratory tested 51 patients for Bilirubin and for Throat Culture the laboratory tested 214 patients from 01/01/2025 to 04/09/2025 when the laboratory ceased testing. 4. During an Interview on 12/04/2025 at 1:30 PM, Testing Personnel #1 confirmed that the LD failed to ensure the laboratory was enrolled in PT for Neonatal Bilirubin and Throat Culture for the 1st event of 2025.</p>
<p>D6047</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview revealed that the Technical Consultant (TC) or a qualified designee failed to observe Patient testing during competency evaluation for four out of five Testing Personnel (TP) for one out of one year reviewed. Findings included: 1. Review of FORM CMS 209 signed by the Laboratory Director on 12/01/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant and Technical Consultant for Hematology and Chemistry specialty and 4 TP (TP#1, TP#2, TP#3 and TP#4). 2. Review of personnel records revealed that competency for TP#1 (Lead Medical Assistant (Lead MA)) observed on 08/14/2025 by TP#2, TP#2 competency observed by TP#1 on 08/14/2025, TP#3 competency observed on 08/14/2025 by TP#1 and TP#4 observed on 09/19/2025 by TP#1. TP#1 did not meet the qualification of a Technical Consultant. 3. During an interview on 12/04/2025 at 12:50 PM, the TP#1 confirmed that the TC failed to observe patient testing observation during annual competency for TP#1, TP#2, TP#3 and TP#4.</p>
<p>D6050</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES</p>

CFR(s): 493.1413(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:

Based on record review and staff interview revealed that the Technical Consultant (TC) or a qualified designee failed to observe direct observation of instrument performance and function check during competency evaluation for four out of five Testing Personnel (TP) for one out of one year reviewed. Findings included: 1. Review of FORM CMS 209 signed by the Laboratory Director on 12/01/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant and Technical Consultant for Hematology and Chemistry specialty and 4 TP (TP#1, TP#2, TP#3 and TP#4). 2. Review of personnel records revealed that competency for TP#1 (Lead Medical Assistant (Lead MA)) observed by TP#2 on 08/14/2025, TP#2 competency overserved by TP#1 on 08/14/2025, TP#3 competency observed on 08/14/2025 by TP#1 and TP#4 observed on 09/19/2025 by TP#1. TP#1 did not qualify for a peer review in competence. 3. During an interview on 08/20/2025 at 12:52 PM, the TP#1 confirmed that the TC failed to observe direct observation of performance of instrument and function check observation during annual competency for TP#1, TP#2, TP#3 and TP#4.