

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0911743	<b>(X3) Date Survey Completed</b>  12/05/2023
<b>Name of Provider or Supplier</b>  North Pinellas Childrens Medical Center Inc	<b>Street Address, City, State</b>  10537 Sr 54, New Port Richey, 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>	An onsite announced CLIA recertification survey was conducted at North Pinellas Children's Medical Center Inc., a laboratory in New Port Richey, FL, on 12/05/2023. The laboratory is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the standard level deficiencies:
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 a review of American Proficiency Institute (API) proficiency testing and interview with the Office Manager, the laboratory failed to have attestation statements signed by the Testing Person and the Laboratory Director for 3 out of 5 events for Hematology/Coagulation Proficiency Testing. (2nd and 3rd event 2022 and 2nd event 2023) The findings include: During a review of API proficiency testing for Hematology/Coagulation for the 3rd Event for 2021, the 1st, 2nd, and 3rd Events for 2022, and the 2nd Event for 2023, it was discovered that attestation statements had not been signed by the Testing Person and the Laboratory Director for the 2nd and 3rd Event for 2022 and the 2nd Event for 2023. A record review of the laboratory's procedure manual revealed a "Proficiency Testing Policy" (dated 8/1/23) that stated, "The individual testing or examining the samples and the Medical Director must attest to the routine integration of samples into the patients' workload using the laboratory's routine methods." On 12/05/23 at 01:30 PM, the Office Manager confirmed she did not have the Testing Person or the Laboratory Director sign the attestation statements.</p>
<b>D5221</b>	<b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b>

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based upon a record review of American Proficiency Institute (API) proficiency testing and an interview with the Office Manager, the Laboratory Director failed to document evaluation of proficiency testing for hematology for two out of five proficiency testing events reviewed. (3rd Event 2021, 1st, 2nd, and 3rd Events 2022, and 2nd Event 2023 ) The findings include: A record review of the API hematology proficiency testing results for the 3rd Event for 2021, the 1st, 2nd, and 3rd Events for 2022, and the 2nd Event for 2023 revealed the Laboratory Director failed to document evaluation of proficiency testing for hematology for the 2nd Event and 3rd Event of 2022. A record review of the laboratory's procedure manual revealed "Proficiency Testing Policy" (dated 8/1/23), that stated "All proficiency testing results should be reviewed by the persons performing the testing and the Medical Director. Signatures attesting this review should be noted on each report summary." On 12/05/23 at 1:35 PM, the Office Manager stated she provided the proficiency testing results to the Laboratory Director but the Laboratory Director had not signed the proficiency tests results.