

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2125440	(X3) Date Survey Completed 11/22/2019
Name of Provider or Supplier North Pinellas Childrens Medical Center - Lutz	Street Address, City, State 23026 Sr 54, Lutz, 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 at North Pinellas Children's Medical Center Inc on 11/22/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing results for white blood cell differential, which includes granulocytes, lymphocytes, and monocytes, erythrocytes (red blood cells - RBC), hematocrit, hemoglobin, mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentrate (MCHC), mean corpuscular volume (MCV), platelet count, and red blood cell distribution width (RDW), and interview with the Office Manager, the Laboratory failed to score at least 80% for one (3rd testing event 2018) out of four (2nd, 3rd testing events in 2018 and 1st, 2nd testing events in 2019) hematology proficiency events reviewed. Findings included: Review of the API 3rd proficiency testing event in 2018 revealed a score of 73% for White Blood Cell differential. Interview on 11/22/2019 at 11:30 AM with the Office Manager confirmed the proficiency testing failure.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing results for hematology and interview with the Office Manager, the Laboratory failed to have documented corrective action for any score less than 100% for three (3rd Event 2018, 1st Event 2019, and 2nd Event 2019) out of four (2nd, 3rd testing events in 2018 and 1st, 2nd testing events in 2019) testing events reviewed. Findings included: Review of the 3rd testing event in 2018 revealed a score of 95% for Hematology, 73% for White Blood Cell Differential, and 60% for Monocytes with no corrective action documented. A review of the 1st testing event in 2019 revealed a score of 98% for Hematology, 93% for White Blood Cell Differential, and 80% for Monocytes with no corrective action documented. A review of the 2nd testing event in 2019 revealed a score of 97% for Hematology, 87% for White Blood Cell Differential, 80% Granulocytes, and 80% for Monocytes with no corrective action documented.

Interview on 11//22/2019 at 11:35 AM with the Office Manager confirmed that no corrective action had been documented when the laboratory scored less than 100%.