

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1037895	(X3) Date Survey Completed 07/03/2018
Name of Provider or Supplier North Pinellas Childrens Medical Center Inc	Street Address, City, State 12780 Racetrack Rd Ste 305, Tampa, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on interview with the Laboratory manager and record review of the Form CMS 209 and American Proficiency Institute (API) proficiency testing, the laboratory failed to rotate proficiency testing to include all testing personnel who perform patient testing for 5 of 5 API Hematology Testing Events reviewed (3rd Event 2016, 1st, 2nd, and 3rd Events 2017, and 1st Event 2018). Findings Included: Review of the Form CMS 209, signed and dated by the Laboratory Director on 06/25/2018, revealed 11 Testing Personnel (#A, B, C, D, E, F, G, H, I, J, K). Review of API Hematology proficiency testing revealed Testing Person #A was the only person who performed the proficiency testing for the 5 of 5 API Hematology Testing Events reviewed (3rd Event 2016, 1st, 2nd, and 3rd Events 2017, and 1st Event 2018). Interview with the Laboratory Manager on 07/03/2018 at 12:15 PM. confirmed that Testing Personnel A was the only person performing proficiency testing even though Testing Person #A-#K all performed patient testing.</p>
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:</p>

Based on review of American Proficiency Institute (API) proficiency testing results and interview with the Laboratory Manager, the laboratory failed to score at least 80% for White Blood Cell (WBC) in 1 out of 5 (3rd testing event 2016 through 1st testing event in 2018) testing events reviewed in the specialty of Hematology. Findings Included: Review of API proficiency testing results revealed the 2nd testing event in 2017 had a score of 40% for WBC. An interview on 07/03/18 at 12:00 PM with the Laboratory Manager confirmed the proficiency testing failure.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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. (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 review of the Hematology instrument manual used by the laboratory, lack of documentation, and interview with the Laboratory Manager, the laboratory failed to document the room temperature and humidity for four months out of two years reviewed (2017-2018). Findings Included: Review of the Hematology instrument manual revealed the test device required an instrument room temperature of 18 - 32 degrees Celsius and a maximum humidity of 80%. Review of the Routine Maintenance Quality Control (Q.C.) and Quality Assurance (Q.A.) Documentation Log revealed no documentation of room temperature and humidity for four months (April 2017, November 2017, January 2018, and May 2018). Interview with the Laboratory Manager on 07/03/2018 at 12:30 PM confirmed that the room temperature and humidity were not being consistently recorded.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the lack of record review and interview with the Laboratory Manager, the laboratory failed to verify the quality control manufacturer's recommended range for

the Hematology controls that were used on the hematology instrument for two out of two years (2017-2018). Findings included: Review of Hematology quality control records revealed the lack of quality controls records for verification of quality control manufacturer's recommended ranges for the new lot of Hematology controls for two out of two years (2017-2018). Interview on 07/03/2018 at 1:00 PM the Laboratory Manager stated the laboratory did not know to verify the quality control manufacturer's recommended ranges for new lot of Hematology controls.