Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1037895	08/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
North Pinellas Childrens Medical Center Inc	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
D0000	An announced CLIA recertification survey was conducted at North Pinellas Children's Medical Center Inc. on 08/26/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review from American Proficiency Institute (API) and interview with the Office Manager, the facility failed to maintain the API hematology proficiency testing report for one (3rd Event 2019) out of 7 testing events reviewed (2018 2nd and 3rd Events, 2019 1st, 2nd, 3rd Events, and 2020 1st and 2nd Events). Findings included: Record review of API proficiency testing documentation revealed there was no evidence that the Hematology API proficiency testing for the 2019 3rd Event had been performed (tests included White Blood Count, Red Blood Count, Hemoglobin, Hematocrit, Platelets, Mean Corpuscular Volume, Red Blood Cell Distribution Width, Mean Concentrate Hemoglobin, Mean Corpuscular Hemoglobin Concentrate, and White Blood Cell Differential). Interview on 08/26/20 at 11:40 a.m. with the Office

	Manager revealed she performed the Hematology 2019 3rd event with guidance from another office's office manager because she had not previously performed proficiency testing. The Office Manager did not know what happened to the paperwork.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on employee competency records and interview with the Office Manager, the laboratory failed to perform competency assessments on 1 (#B) out of 5 (#A, B, C, D, and E) Testing Personnel since her date of hire. Findings included: A review of the CMS 209, Laboratory Personnel Report, revealed Employee #B was a Testing Personnel. A review of employee competency records for 2018 through 2020 revealed no competency records were present for Testing Personnel #B. Testing Personnel #B was hired on 01/03/20. Interview on 08/26/20 at 11:30 a.m. with the Office Manager (Testing Personnel #B) revealed she forgot to have her 6 month competencies performed.
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 lack of documentation and interview with the Office Manager, the laboratory failed to verify manufacturer's recommended ranges for Hematology controls, before testing patients, on the hematology instrument for two out of two years (2018-2020). Findings included: An attempt to review Hematology quality control records revealed no quality controls records were present to verify manufacturer's recommended ranges for the new lot of quality controls for the Hematology instrument for two out of two years (2018-2020). Interview on 08/26 /2020 at 1:00 PM with the Office Manager revealed she did not know to verify the quality control manufacturer's recommended ranges for a new lot of Hematology controls before testing with patients. This is a repeat deficiency.