Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1037895	12/13/2022
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 Children's Medical Center Inc. on 12/07/2022 - 12/13/2022 The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were cited: D5400 - Analytic Systems
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document room temperatures where waived cartridges, test kits, and testing equipment were being stored and waived testing was being performed for Strep A, Influenza A and B, Respiratory Syncytial Virus (RSV), FLU + SARS Antigen, and SARS Antigen tests for two of two years reviewed (October 2020 - December 2022). Findings Included: Review of the Manufacturer Instructions (MI) for the Strep A, Influenza A and B, RSV, Flu + SARS Antigen, and SARS Antigen Cartridges used on the Sofia analyzer revealed a storage temperature of "15 - 30 degrees Celsius." Review of the MI for the SARS Antigen test revealed "Specimens processed Reagent Tubes (rehydrated) have an in-use stability of up to 1 hour at room temperature, 59 to 86 degrees Fahrenheit (15 - 30 degrees Celsius), out of sunlight." Additionally, the laboratory conducted waived urinalysis testing. Review of the MI for operating conditions of the urinalysis instrument revealed "Optimum Operating Temperature Range was 22 to 26 degrees Celsius." Review of the laboratory's temperature logs revealed no temperature log was maintained for the room where the waived testing was being performed and waived

	test kits, cartridges, and equipment were stored. On 12/07/22 at 3:00 PM, the Office Manager stated that the testing personnel did not know the room temperature needed to be documented in the room where the waived testing was being performed.
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 proficiency record review and interview with the Laboratory Director, the laboratory failed to retain documentation of signed attestation statements and documentation that proficiency testing (PT) results had been reviewed for Hematology for 9 out of 9 testing events reviewed for two of two years reviewed (2020 - 2022). Findings included: Record review of the laboratory's procedure manual signed by the Laboratory Director on 07/24/2020 revealed a "Proficiency Testing Policy" with "Proficiency Testing Procedure and Guidelines" to include: "The laboratory will maintain a copy of all records, including a copy of the proficiency testing program report program forms used by the laboratory to record proficiency testing results, including the attestation statement provided by the proficiency testing program signed by the analyst and the Medical Director. The policy section for "Evaluation of Proficiency Testing Results" showed "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." Review of the American Proficiency Institute (API) instructions revealed that "Testing Personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years." Review of 9 proficiency records to include API 3rd Event 2020, API 1st, 2nd, and 3rd Event 2021, API 1st, 2nd, and 3rd Event 2022, 2022 Off-Schedule PT for Medical Laboratory Evaluation (MLE) submitted 06/06/2022, and 2022 Off Schedule PT Evaluation Wisconsin State Laboratory of Hygiene (WSLH) submitted 06/30/2022 had not been signed by the Lab Director or Testing personnel and did not include documentation that PT test results had been reviewed by the laboratory director or staff. Interview with the Laboratory Director on 12/07/2022 at 12:30 PM. revealed she did not know that she and the testing personnel needed to sign the attestation statements, and she needed to document that she had reviewed the proficiency testing results along with the persons performing the testing.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and

	procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to document their quality assessment activity for unsuccessful Hematology proficiency testing that was cited during a desk review survey of the laboratory's proficiency test results on February 10, 2022. Findings included: Review of the Plan of Correction that the Laboratory Director signed and dated on 03/11/2022 for a desk review survey of the laboratory's proficiency test results conducted 2/10/22 revealed the following remedial measures were instituted to prevent reoccurrence: "A checklist, requiring two or more signatures, has been implemented to ensure all steps to achieving accurate proficiency testing will occur moving forward." The Plan of Correction also noted the corrective action would be monitored to ensure the deficient practice does not recur which included, "Additional formal training will be provided to all Testing Personnel." Record review of the "Proficiency Test Tracking" form to show that all steps were followed to achieve accurate proficiency testing had only been completed for one event following the 2/10/2022 survey (American Proficiency Institute (API) 1st Event of 2022) and was not conducted for the API 2nd and 3rd events of 2022. Record review of employee training and competency records did not reveal any evidence that additional formal training for proficiency testing was provided to testing personnel following the 2/10/22 survey. Interview on 12/7/2022 at 12:40 PM with the Laboratory Director revealed she did not know why the laboratory failed to follow their Plan of Correction by completing the "Proficiency Test Tracking" form for the API 2022 2nd and 3rd Event and why "Additional formal training" for proficiency testing was not documented for testing personnel.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of documentation, review of the procedure manual, 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 reviewed (2020 - 2022). See D5469
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, review of the procedure manual, 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 reviewed (2020-2022). 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 (2020 - 2022). Record review of the policy manual signed by the Laboratory Director on 07/24/20 revealed the "Quality Control Policy" which stated "Manufacturer's ranges are used for control values." Interview on 12/07/2022 at 2:50 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 from 08/26/2020 and 07/03/2018.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to review 9 out 9 Hematology proficiency testing (PT) events (American Proficiency Institute (API) 3rd Event 2020, API 1st, 2nd, and 3rd Event 2021, Off-Schedule Medical Laboratory Evaluation (MLE) PT submitted 06/06/2022, Off-Schedule Wisconsin State Laboratory of Hygiene (WSLH) PT submitted 06/30/2022, and API 2022 1st, 2nd, and 3rd Events) for two of two years reviewed (2020 -2022). Findings included: Review of the laboratory's hematology PT for 9 events showed no documentation that PT results were reviewed. Interview on 12/07/2022 at 12:30 PM with the Laboratory Director revealed she did not know that she needed to document she had reviewed PT results. (See D2015)