

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0298601	(X3) Date Survey Completed 10/15/2019
Name of Provider or Supplier North Pinellas Childrens Medical Center Inc	Street Address, City, State 31860 Us Hwy 19 N, Palm Harbor, 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 on 10/15/19. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Manager the laboratory failed to document the daily maintenance on the Sysmex XP-300 hematology analyzer for 6 (January, April, August 2019 and February, June, October 2018) out of 6 months reviewed. Findings Included: Review of the instrument manual for the Sysmex XP-300 Hematology analyzer revealed the daily maintenance included: Perform Shutdown, Verify Background, Verify Vacuum Pressure, Check Trap Chamber, and Perform Quality Control. The instrument manual provided a "Maintenance Log" where each task should be checked each day of testing. Review of maintenance logs for January, April, and August of 2019 and February, June, and October of 2018 revealed that no daily maintenance had been checked off as performed. On 10/15/19 at 11:10 AM, the Clinical Manager confirmed that the daily maintenance was not documented.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of</p>

all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Clinical Manager, the Technical Consultant failed to perform the Testing Personnel competency assessments for 20 (#A-#T) out of 20 Testing Personnel reviewed. Findings Included: Review of the Testing Persons' personnel files revealed that the Clinical Manager signed off on the competency evaluations for all 20 Testing Personnel. The Clinical Manager does not meet the qualifications to perform the duties of the Technical Consultant. Interview on 10/15/19 at 11:30 AM with the Clinical Manager, confirmed that the Technical Consultant did not perform or sign the Testing Personnel competency evaluations.