Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0698512	09/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Windermere Pediatrics Pa	7635 Ashley Park Ct Ste 501, Orlando, 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	A Recertification survey was conducted on September 20, 2019. Windermere Pediatrics clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2121	HEMATOLOGY CFR(s): 493.851(a) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to attain a score of at least 80 percent on 3 analytes for the 1st of 3 testing events in 2018 in the specialty of Hematology. Findings: Review of American Academy of Family Physicians (AAFP) proficiency testing results showed for the 1st testing event in 2018 the laboratory received a 60% for Red Blood Cell, 60% for Hemoglobin and 60% for Hematocrit. During an interview on 9/20/19 at 10:01 AM, the Laboratory Director confirmed the proficiency testing scores were unsatisfactory.
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 record review and interview, the laboratory failed to perform quality control lot to lot comparisons from 9/20/17 to 9/20/19 for hematology. Findings: Review of the quality control logs showed that there were no lot to lot comparisons of the hematology controls from 9/20/17 to 9/20/19 for the Horiba ABX Micros 60 Hematology analyzer. During an interview on 9/20/19 at 11:36 AM, Testing Personnel D acknowledged that the laboratory did not perform quality control lot to lot comparisons.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory reported patient results on 2 days between 9/20/17 and 9/20/19 when controls run on the Horiba ABX Micros 60 Hematology analyzer were not acceptable. Findings: Review of quality control (QC) records on 1/16/18 showed that 2 (low and high) out of three (low, normal and high) levels of controls for Red Blood Cell Counts (RBC) were out of the acceptable range. The laboratory's hematology analyzer reported the RBC low control as 2.42, and high control as 5.95 for lot number MX409. The package insert for the hematology controls lot number MX409 lists the acceptable range for the RBC low control as 2.11 - 2.41, and high as 5.51 - 5.91. Review of quality control (QC) records on 3/6/18 showed that 2 (normal and high) out of three (low, normal and high) levels of controls for White Blood Cell Counts (WBC) were out of the acceptable range. The laboratory's hematology analyzer reported the WBC normal control as 6.0, and high control as 15.0 for lot number MX410. The package insert for the hematology controls lot number MX410 lists the acceptable range for the WBC normal control as 7.0- 8.6, and high as 18.9 - 22.1. Review of patient logs for hematology testing showed that test results were reported for one patient on 1/6/18 and one patient on 3/6 /18 on days which two controls were not in the acceptable range. During an interview on 9/20/19 at 10:50 AM, the Laboratory Director confirmed the controls were out and hematology test results were reported for one patient on 1/16/18 and one patient on 3/6 /18.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's patient reports failed to list the name and address of the laboratory where the hematology testing was performed for 5 out of 5 patient (#1, #2, #3, #4, and #5). Findings: Review of the hematology test results for patient #1, #2, #3, #4, and #5 showed that the laboratory's name and address was not listed on the reports. During an interview on 9/20/19 at 11:59 AM, the Laboratory Director acknowledged that the hematology reports did not have the name and address of where the hematology tests were preformed.