Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2062945	03/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Family First Pediatrics	2830 Casa Aloma Way, Winter Park, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have all testing personnel rotate through the testing of proficiency testing samples for 2 of 2 years (2017 and 2018) reviewed. Findings: Review of the American Proficiency Institute (API) proficiency testing attestation forms showed that Testing Personnel A performed all the proficiency testing for 2017 and 2018. Review of the CMS-209 form title "Laboratory Personnel Report (CLIA)" that was signed and dated by the Laboratory Director on 2/18/19 listed 3 testing personnel. During an interview on 3/5 /19 at 9:55 AM, Testing Personnel A stated that she had performed all the proficiency testing and that Testing Personnel B was employed at the time and could have performed some of the proficiency testing. Testing Personnel A also stated that Testing Personnel C was recently hired and not trained to perform proficiency testing yet.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by:

	Based on observation, interview and record review, the laboratory failed to consistently document the daily maintenance performed on the Horiba Micros 60 hematology analyzer from 3/5/17 to 3/5/19. Findings: Review of the user manual for the hematology analyzer noted that cleaning procedures were required daily to maintain optimum performance of the analyzers. Observations and review of the maintenance records stored in the computer that was connected to the hematology analyzer showed that the testing personnel failed to record the performance of the daily maintenance. Daily maintenance was recorded for 1 day of the 4 months of maintenance records viewed on the computer. During an interview on 3/5/19 at 11:20 AM, Testing Personnel A stated that the maintenance was performed but not recorded regularly.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration verification every six months between 5/3/17 and 9/11/18. Findings: Review of calibration verification records for the Horiba Micro 60 hematology analyzer revealed that calibration verifications were performed on 5/3/17 and 9/1/18 (16 months apart). During an interview on 3/5/16 at 10:38 AM, Testing Personnel A confirmed that they missed performing the calibrations.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of 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, the laboratory's Technical Consultant failed to perform competency evaluations on Testing Personnel A for 2 out of 2 years, and on Testing Personnel B for 1 out of 2 years for the years (2017 and 2018) reviewed. The "Laboratory Personnel Report" signed and dated on 2/18/19 showed that the Laboratory Director was also the Technical Consultant. Review of employee competencies revealed that Testing Personnel A, did not have any competency evaluations performed in 2017 or 2018. Testing Personnel B did not have a competency evaluation performed in 2018. During an interview on 2/5/19 at 10:47 AM, Testing Personnel A acknowledged that a competency evaluation was not performed on herself in 2017 and 2018, and that Testing Personnel B did not have a competency evaluation in 2018.