

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2062945	(X3) Date Survey Completed 04/08/2021
Name of Provider or Supplier Family First Pediatrics	Street Address, City, State 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
D0000	A recertification survey was conducted on April 8, 2021. Family First Pediatrics clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have all testing personnel rotate through performance of proficiency testing (PT) samples for 3 of 3 events (1st, 2nd, 3rd) in 2020 for the specialty of hematology. This is a repeat deficiency from the recertification survey on 03/05/2019. Findings: Review of the American Proficiency Institute PT showed Testing Personnel A was the only person to sign the attestation forms as the person performing the PT. Attestations were signed by Testing Personnel A on the following dates: 2020 1st event - 03/25/2020 2020 2nd event - 07/14/2020 2020 3rd event - 11/23/2020 Review of the procedure titled, Proficiency Testing noted "Both external proficiency testing and alternative performance assessment samples must be integrated within the routine laboratory workload, and analyzed by personnel who routinely test patient samples, using primary method systems." On 04/08/2021 at 11:27 AM, Testing Personnel A stated she was the only person who performed PT in 2020. On 04/08/2021 at 11:45 AM, Testing Personnel B stated she started work on 08/26/2019. On 04/08/2021 at 11:48 AM, Testing Personnel C stated she started work on 06/18/20.</p>
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings: Cross Reference D6016. Based on record review and interview, the Laboratory Director failed to ensure all testing personnel rotated through performance of proficiency testing (PT) samples for 3 of 3 events (1st, 2nd, 3rd) in 2020 for the specialty of hematology.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure all testing personnel rotated through the performance of proficiency testing (PT) samples for 3 of 3 events (1st, 2nd, 3rd) in 2020 for the specialty of hematology. Findings: Review of the American Proficiency Institute PT showed that Testing Personnel A was the only person to sign the attestation forms as the person performing the PT. Attestations were signed by Testing Personnel A on the following dates: 2020 1st event - 03/25/2020 2020 2nd event - 07/14/2020 2020 3rd event - 11/23/2020 Review of the procedure titled Proficiency Testing noted "Both external proficiency testing and alternative performance assessment samples must be integrated within the routine laboratory workload, and analyzed by personnel who routinely test patient samples, using primary method systems." On 04/08/2021 at 11:27 AM, Testing Personnel A stated she was the only person who performed the PT in 2020. On 04/08/2021 at 11:45 AM, Testing Personnel B stated she started on 08/26/2019. On 04/08/2021 at 11:48 AM, Testing Personnel C stated she started on 06/18/20.